18-03449-E

March 26 2018


Dear FOIA Office:

Under the Freedom of Information Act (FOIA), please send a copy of the following: **A copy of:**

**Exhibit 10.1 to the form 8-K filed by CELL GENESYS INC on March 31, 2008** In the event confidential treatment has not expired provide the specific date for which confidential treatment is still in effect. I do not need a copy of the order. We authorize up to $61.00 in processing fees.

Thank You,

Paul D'Souza
Editor - Deals

Clarivate Analytics Friars House, 160 Blackfriars Road London, UK SE1 8EZ
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paul.dsouza@clarivate.com

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
STATION PLACE
100 F STREET, NE
WASHINGTON, DC 20549-2465

Office of FOIA Services

April 18, 2018

Mr. Paul D'Souza
Clarivate Analytics
160 Blackfriars Road
London, UK SE1 8EZ

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-03449-E

Dear Mr. D'Souza:

This letter is in response to your request, dated and received in this office on March 26, 2018, for Exhibit 10.1 to the form 8-K, filed by Cell Genesys, Inc., on March 31, 2008.

The search for responsive records has resulted in the retrieval of 106 pages of records that may be responsive to your request. They are being provided to you with this letter.

If you have any questions, please contact me at fultonc@sec.gov or (202) 551-8186. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Lizzette Katilius as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

Charlotte Fulton
FOIA Research Specialist

Enclosure

10.1

# DEVELOPMENT AND COMMERCIALIZATION COLLABORATION AGREEMENT

This **DEVELOPMENT AND COMMERCIALIZATION COLLABORATION AGREEMENT** (the **"Agreement"**) is entered into as of March 31, 2008 (the "**Effective Date**") between **CELL GENESYS, INC.**, a Delaware corporation, with its principal place of business at 500 Forbes Boulevard, South San Francisco, CA 94080 (**"Cell Genesys"**), and **TAKEDA PHARMACEUTICAL COMPANY LIMITED**, a company incorporated under the laws of Japan, with its principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka, 540-8645, Japan (**"Takeda"**). Cell Genesys and Takeda are sometimes referred to herein individually as a **"Party"** and collectively as the **"Parties."**

## RECITALS

**WHEREAS**, Cell Genesys is developing its proprietary GVAX immunotherapy product for the treatment of prostate cancer;

**WHEREAS**, Takeda possesses substantial resources and expertise in the development, marketing, and commercialization of pharmaceutical products for the treatment of cancer in the Licensed Territory (as defined below); and

**WHEREAS**, Takeda desires to collaborate with Cell Genesys on the further development of the Product (as defined below) in the Field (as defined below) through regulatory approval in the Licensed Territory, and to obtain commercialization rights to the Product in the Field in the Licensed Territory and Cell Genesys is willing to so collaborate and to grant such rights on the terms and conditions hereof.

**NOW THEREFORE**, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

## ARTICLE 1

## DEFINITIONS

**1.1 "Additional Product"** means any (i) [new formulation, dosage form, improvement, or mode of administration of the Product described on Exhibit A], (ii) pharmaceutical composition that [contains a derivative or modified form of Cell Genesys' irradiated GM-CSF-secreting prostate tumor clonal cell lines designated as CG8711 and CG1940]; or (iii) [Cell Genesys' cellular immunotherapy product that comprises live tumor cells that are genetically modified to express a cytokine or other immune system adjuvant].

**1.2 "Additional Studies"** means all Non-Clinical Studies and clinical studies other than the VITAL Studies or the Currently Ongoing Studies, whether conducted prior to or following Regulatory Approval of the Product, pertaining to the use of the Product in the Field for the Licensed Territory, including: Phase 1, 2, 3 or 4 Clinical Studies or pivotal studies (including studies for additional indications or label expansion); investigator-sponsored trials, safety or surveillance studies; pharmacoeconomic studies; pharmacoepidemiology studies; reimbursement studies; and other studies.

**1.3 "Affiliate"** means, with respect to a particular Party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of fifty percent (50%) or more of the voting stock of such entity, or by contract or otherwise. Notwithstanding anything to contrary, in no event shall TAP Pharmaceutical Products, Inc. be considered an Affiliate of Takeda until such time as TAP Pharmaceutical Products, Inc. may become an indirectly wholly-owned subsidiary of Takeda.

**1.4 "Best Knowledge"** means, as applied to a Party, that the applicable Party's [senior management with operational responsibility for the Development or Commercialization of the Product] is actually aware of a particular fact or other matter [following reasonably diligent inquiry of its management employees with primary responsibility for the applicable subject matter].

**1.5 "Cell Genesys Group"** has the meaning set forth in Section 11.1.

**1.6 "Cell Genesys Indemnitees"** has the meaning set forth in Section 11.2.

**1.7 "Cell Genesys Know-How"** means all Information that is Controlled by Cell Genesys as of the Effective Date or during the Term and is necessary or reasonably useful for the Development or Commercialization of the Product in the Field in accordance with the terms of this Agreement. For clarity, Cell Genesys Know-How includes Information relating to previously conducted Non-Clinical Studies for the Product and clinical studies, Currently Ongoing Studies and VITAL Studies, but excludes Information contained within the Cell Genesys Patents.

**1.8 "Cell Genesys Patent"** means any Patent that (a) is Controlled by Cell Genesys as of the Effective Date or at any time during the Term, and (b) would, but for the license granted by Cell Genesys hereunder, be infringed by the Development, Manufacture, use, sale, offer for sale, having sold, Distribution, import, or any other Commercialization of the Product by or on behalf of Takeda or its sublicensee(s) in the Field. Cell Genesys Patents shall include without limitation (i) Cell Genesys' interest in any Joint Patent in the Licensed Territory, (ii) those Patents listed on Exhibit B-1, and (iii) any patent issuing from an application claiming priority thereto or otherwise continuing therefrom.

**1.9 "Cell Genesys Technology"** means the Cell Genesys Patents and Cell Genesys Know-How.

**1.10 "CG Marks"** has the meaning set forth in Section 6.9(b).

**1.11 "Claims"** has the meaning set forth in Section 11.1.

**1.12 "Clinical Supply Costs"** means the cost actually incurred by Cell Genesys in the Manufacture of Product for clinical supply calculated as the sum of: [(i) direct labor costs (salaries, wages and employee benefits); (ii) direct raw materials and supply costs; (iii) direct

external quality and in-process control costs; (iv) related facility and Quality Assurance/Quality Control costs (except those costs arising from Cell Genesys' errors unrelated to spoilage); and (v) Distribution costs].

**1.13** **"CMC"** means chemistry, manufacturing and controls as specified by the FDA.

**1.14** **"Co-Promotion Agreement"** has the meaning set forth in Section 6.12(c)(i).

**1.15** **"Co-Promotion Option"** has the meaning set forth in Section 6.12(a).

**1.16** **"Commercialization,"** with a correlative meaning for **"Commercialize"** and **"Commercializing,"** means all activities undertaken before and after obtaining Regulatory Approvals relating specifically to the pre-launch, launch, promotion, Detailing, medical education and medical liaison activities, publication, marketing, pricing, reimbursement, sale, and distribution of the Product, including: (a) strategic marketing, sales force detailing, advertising, medical education and liaison, and market and Product support; and (b) all customer support, Product distribution, invoicing and sales activities.

**1.17** **"Commercialization Plan"** has the meaning set forth in Section 6.2.

**1.18** "**Committee**" has the meaning set forth in Section 3.4(a).

**1.19** **"Confidential Information"** means, with respect to a Party, all reports and other Information of such Party that is disclosed to the other Party under this Agreement, whether in oral, written, graphic, or electronic form. All Information disclosed by either Party pursuant to the Confidential Disclosure Agreement between the Parties dated January 17, 2007 shall be deemed to be such Party's Confidential Information disclosed hereunder.

**1.20** **"Control"** means, with respect to any material, Information, or intellectual property right, that a Party (i) owns or (ii) has a license to such material, Information, or intellectual property right and, in each case, has the ability to grant to the other Party access, a license, or a sublicense (as applicable) to the foregoing on the terms and conditions set forth in this Agreement without violating the terms of any then-existing agreement or other arrangement with any Third Party.

**1.21** **"Currently Ongoing Studies"** means the following clinical studies: (i) [G-0016: "A Phase 1 Dose Escalation Trial of MDX-010 in Combination with CG1940 and CG8711 in Patients with Metastatic Hormone-Refractory Prostate Cancer" (including any amendment thereto pending as of the Effective Date)]; and (ii) [I-0057: "Phase II Trial of Neoadjuvant Docetaxel and CG1940 and CG8711 Followed by Radical Prostatectomy in Patients with High-Risk, Clinically Localized Prostate Cancer." ]

**1.22** "**Designated Executive**" has the meaning set forth in Section 3.1(b).

**1.23** **"Detail"** means a face-to-face or electronic presentation and any associated in-service training regarding the features of the Product by a Party's sales representative to one or several medical professional(s) having prescribing authority in the Field (including pharmacists),

as well as to other individuals or entities that have significant impact or influence on prescribing decisions in the Field.

**1.24 "Develop"** or **"Development"** means all activities relating to preparing and conducting and documenting Non-Clinical Studies, human clinical studies, and regulatory activities (*e.g.*, regulatory applications) with respect to the Product, but excluding in each case any activities relating to the Manufacture of the Product.

**1.25 "Diligent Efforts"** means, with respect to a Party's obligation under this Agreement to Develop or Commercialize the Product, efforts and resources normally used by a similarly situated company in the pharmaceutical industry for a product owned by or licensed to it, and activities related to the development and commercialization of such product, which is of similar commercial potential at a similar stage in its development or product lifecycle, taking into account various issues, such as its safety and efficacy, product profile, cost to develop, the time required to complete development, the competitiveness of the marketplace, the company's patent position with respect to such product, the third-party patent landscape relevant to the product, the regulatory structure involved, the likelihood of regulatory approval, the anticipated or actual profitability of the applicable product, and all other relevant factors, all as measured by the facts and circumstances at the time such efforts are due. Diligent Efforts requires, with respect to such an obligation, that the Party: (a) promptly assign responsibility for such obligation to specific employee(s) who are held accountable for progress and monitor such progress on an on-going basis, (b) set and consistently seek to achieve specific and meaningful objectives for carrying out such obligation, and (c) consistently make and implement decisions and allocate resources designed to advance progress with respect to such objectives.

**1.26 "Distribution,"** with a correlative meaning for **"Distribute"** and **"Distributing,"** means the materials, packaging activities, processes, procedures specifically designed and necessary for warehousing, transferring and handling Product from Cell Genesys' manufacturing facility in Hayward, California, or any other manufacturing facility designated in accordance with the terms of this Agreement or the Supply Agreement, up to and including the physicians' office.

**1.27 "Dollar"** means a U.S. dollar, and "$" shall be interpreted accordingly.

**1.28 "FD&C Act"** means the U.S. Federal Food, Drug and Cosmetic Act, as amended.

**1.29 "FDA"** means the U.S. Food and Drug Administration or any successor entity.

**1.30 "Field"** means the prevention, diagnosis, and treatment of prostate cancer and other urological neoplasms or urological hyperplasias.

**1.31 "First Commercial Sale"** means the first sale to a Third Party of a Product in a given regulatory jurisdiction after Regulatory Approval has been obtained in such jurisdiction.

**1.32 "Generic Version"** has the meaning set forth in Section 8.4(c).

**1.33 "Good Clinical Practices"** or **"GCP"** means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in the guidelines entitled

"Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures in jurisdictions outside the U.S., as they may be updated from time to time, including applicable quality guidelines promulgated under the International Conference on Harmonization ("ICH").

**1.34 "Good Laboratory Practices"** or **"GLP"** means the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, and comparable regulatory standards in jurisdictions outside the U.S., as they may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

**1.35 "Good Manufacturing Practices," "cGMP"** or **"GMP"** means the then-current good manufacturing practices as required by the Regulatory Authority in the Shared Territory and ROW Territory, as applicable, for the manufacture and testing of pharmaceutical materials, and comparable laws or regulations applicable to the manufacture and testing of pharmaceutical materials in jurisdictions in the Licensed Territory, as they may be updated from time to time, including applicable quality guidelines promulgated under the ICH and other applicable regulations.

**1.36 "Governmental Authority"** means any multi-national, federal, state, local, municipal, provincial or other government authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

**1.37 "GVAX"** means (i) [an immunotherapy comprising at least one proliferation-incompetent, live tumor cell that is genetically modified to secrete at least one of a cytokine, an adhesion molecule and an accessory molecule], and (ii) [any uses or manufacture thereof; in each case of (i) and (ii) above to the extent claimed by any Patent Controlled by Cell Genesys during the Term or to the extent covered by Cell Genesys Know-How as of the Effective Date].

**1.38 "IND"** means (a) an Investigational New Drug application as defined in the FD&C Act and applicable regulations promulgated hereunder by the FDA, or (b) the equivalent application to the equivalent Governmental Authority in any other regulatory jurisdiction outside the U.S., the filing of which is necessary to commence or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction.

**1.39 "Indemnified Party"** has the meaning set forth in Section 11.3.

**1.40 "Indemnifying Party"** has the meaning set forth in Section 11.3.

**1.41 "Information"** means any data, results, technology, business and financial information and information of any type whatsoever, in any tangible or intangible form, including, without limitation, know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulations, formulae, materials or compositions of matter of any type or kind (patentable or otherwise), software, algorithms, marketing reports, expertise, technology, test data (including pharmacological, biological, chemical, biochemical, clinical study data and data resulting from Non-Clinical Studies), CMC information, stability data, other study data and procedures.

**1.42 "Initial Threshold"** has the meaning set forth in Section 8.4(c).

**1.43 "Internal FTE Costs"** means internal personnel costs incurred by Cell Genesys, including compensation and benefits.

**1.44 "Joint Commercial Committee"** or **"JCC"** means the committee formed by the Parties as described in Section 3.3.

**1.45 "Joint Development Committee"** or **"JDC"** means the committee formed by the Parties as described in Section 3.2.

**1.46 "Joint Inventions"** has the meaning set forth in Section 9.1.

**1.47 "Joint Patent"** has the meaning set forth in Section 9.3(c).

**1.48 "Joint Steering Committee"** or **"JSC"** means the committee formed by the Parties as described in Section 3.1.

**1.49 "Laws"** means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign.

**1.50 "License Agreement"** has the meaning set forth in Section 8.10.

**1.51 "Licensed Territory"** means the ROW Territory and the Shared Territory.

**1.52** "**Manufacture**" with a correlative meaning for **"Manufacturing,"** means all activities related to the manufacturing of a pharmaceutical product, or any ingredient thereof, including manufacturing Product in finished form for Development, manufacturing finished Product for Commercialization, packaging, in-process and finished product testing, release of product or any component or ingredient thereof, quality assurance activities related to manufacturing and release of product, all stability studies including those for registration, the development and validation of testing methods used for, but not limited to, release test, stability test and every testing method for commercial use, preparation of the documents of any "Manufacture" related reports in "common technical document" form described in ICH, and documents necessary for clinical and market authorization development including but not limited to development history reports for drug substance and drug product, comparability studies and reports, in the Licensed Territory and regulatory activities related to any of the foregoing.

**1.53 "Marketing Authorization Application"** or **"MAA"** means an application to the appropriate Regulatory Authority for approval to market the Product (but excluding pricing approval) in any particular jurisdiction.

**1.54** "**MHLW**" means the Ministry of Health, Labor and Welfare of Japan, or any successor entity.

**1.55 "Net Sales"** means, with respect to a particular time period, the total amounts invoiced by Takeda, its Affiliates and their respective sublicensees for sales of Products made

during such time period to unaffiliated Third Parties, less the following deductions in each case to the extent reasonable and customary and actually allowed or incurred with respect to such sales:

**(a)** discounts, including cash and quantity discounts (including early payment discounts), charge-back payments, and rebates actually granted or administrative fees actually paid to trade customers, patients (including those in the form of a coupon or voucher), managed health care organizations, pharmaceutical benefit managers, group purchasing organizations, federal, state, or local government and the agencies, purchasers and reimbursers of managed health organizations, pharmaceutical benefit managers, group purchasing organizations, or federal, state or local government;

**(b)** credits or allowances actually granted upon prompt payment or claims, damaged goods, rejections or returns of such Product, including in connection with recalls;

**(c)** freight, postage, shipping, transportation and insurance charges, in each case actually allowed or paid for delivery of Product, to the extent billed or recognized;

**(d)** taxes (other than income taxes), duties, tariffs or other governmental charges levied on the sale of such Product, including, without limitation, value-added and sales taxes.

**(e)** amounts actually paid to Third Party distributors solely in respect of the sale of Product; and

**(f)** the actual amount of any write-offs for bad debt; provided that an amount subsequently recovered and identified with the invoice for which the amount had been written off will be thereafter treated as Net Sales. Takeda will use Diligent Efforts to minimize bad debts.

Notwithstanding the foregoing, amounts invoiced by Takeda, its Affiliates, or their sublicensees for the sale of Product among Takeda, its Affiliates or their respective sublicensees for resale shall not be included in the computation of Net Sales hereunder and such amounts shall be accounted for only once. For purposes of determining Net Sales, a "sale" shall not include reasonable transfers or dispositions, at no cost, as samples or for charitable purposes, or transfers or dispositions at no cost for Non-Clinical Studies, clinical or regulatory purposes. Net Sales shall be accounted for in accordance with standard Takeda practices for operation by Takeda, its Affiliates or sublicensees, as practiced in the relevant country in the Licensed Territory, but in any event in accordance with (i) generally accepted accounting principles, consistently applied in such country in the Licensed Territory (other than the Shared Territory), and (ii) U.S. generally accepted accounting principles, consistently applied, in the Shared Territory. Product sales are recognized when persuasive evidence of an arrangement with a Third Party at a fixed or determinable price exists, title and risk of loss has passed to the Third Party (generally upon receipt by the Third Party, and collectibility of amounts billed is reasonably assured). Provisions for discounts, rebates, chargebacks, and estimated returns shall be recorded at the time of sale.

Takeda, its Affiliates, and their respective sublicensees will sell Products as stand-alone products and will not sell such Products as part of a bundle with other products or offer packaged

arrangements to customers that include Products, except with Cell Genesys' prior written consent.

**1.56 "Non-Clinical Studies"** means *in vivo* animal or *in vitro* pharmacology, pharmacokinetic, or toxicology testing.

**1.57 "Other Collaboration Data"** has the meaning set forth in Section 4.7.

**1.58 "Other Regulatory Materials"** has the meaning set forth in Section 5.6.

**1.59 "Out-of-Pocket Costs"** means any reasonable amounts paid by Cell Genesys to Third Parties in accordance with the then-current Shared Territory Development Plan (for the Shared Territory) and as incurred for the ROW Territory for activities pursuant to Section 4.4(c), in each case in connection with activities or services conducted by such Third Parties, including but not limited to, contract research, laboratory services, consulting services, shipping and distribution.

**1.60 "Patent Challenge"** has the meaning set forth in Section 9.8(c).

**1.61 "Patent Term Extension"** means any term extensions, supplementary protection certificates, Regulatory Exclusivity and equivalents thereof offering patent or patent-like protection beyond the initial term with respect to any issued Patents.

**1.62 "Patents"** means (a) pending patent applications (and patents issuing therefrom), issued patents, utility models and designs; and (b) reissues, substitutions, confirmations, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, continuations-in-part, or divisions of or to any patents, patent applications, utility models or designs, in each case being enforceable within the applicable territory.

**1.63 "Phase 1 Clinical Trial"** means a clinical trial of a pharmaceutical product on healthy subjects or patients with the primary purpose of determining safety, metabolism and pharmacokinetic properties and clinical pharmacology of such product.

**1.64 "Phase 2 Clinical Trial"** means a clinical trial of a pharmaceutical product on patients, including possibly pharmacokinetic studies, the principal purposes of which are to make a preliminary determination that such product is safe for its intended use and to obtain sufficient information about such product's efficacy to permit the design of further clinical trials.

**1.65 "Phase 3 Clinical Trial"** means a clinical trial on sufficient numbers of patients, which trial(s) are designed to (a) establish that a drug is safe and efficacious for its intended use; (b) define warnings, precautions and adverse reactions that are associated with the drug in the dosage range to be prescribed; and (c) support approval of an application to a Regulatory Authority for the commercial marketing of such drug.

**1.66 "Phase 4 Clinical Trial"** means a clinical trial of a pharmaceutical product conducted after Regulatory Approval of the product has been obtained from an appropriate Regulatory Authority, which trial is (a) conducted voluntarily by a Party to enhance marketing or scientific knowledge of such product (*e.g.*, for expansion of product labeling or dose

optimization), or (b) conducted as a condition for sale or post-approval commitment to or requirement of a Regulatory Authority. For clarity, a human clinical trial conducted to support a new Regulatory Approval for a new indication of a product shall not be considered a Phase 4 Clinical Trial

**1.67 "Post-Launch Window"** has the meaning set forth in Section 6.12(a).

**1.68 "Pre-Launch Window"** has the meaning set forth in Section 6.12(a).

**1.69 "Product"** means (a) a pharmaceutical composition, [in any dosage form or form of administration], that contains Cell Genesys' [irradiated GM-CSF-secreting prostate tumor clonal cell lines designated as CG8711 and CG1940] described on Exhibit A, [whether administered together as a single pharmaceutical product or co-administered together with one or more other biologic or pharmaceutically active products or agents], or (b) any Additional Product.

**1.70 "Product Complaint"** means any written, verbal or electronic expression of dissatisfaction regarding the Product, including without limitation reports of actual or suspected product tampering, contamination, mislabeling or inclusion of improper ingredients.

**1.71 "Product Infringement"** has the meaning set forth in Section 9.5(b).

**1.72 "Product Mark"** has the meaning set forth in Section 6.9(a).

**1.73 "Quality Agreement"** has the meaning set forth in Section 7.3.

**1.74 "Regulatory Approval"** means all approvals necessary, including price approval, for the commercial sale of the Product for the Field in a given country or regulatory jurisdiction.

**1.75 "Regulatory Authority"** means, in a particular country or jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction.

**1.76 "Regulatory Exclusivity"** means any exclusive marketing rights or data exclusivity rights conferred by any Governmental Authority with respect to the Product, in a country under the jurisdiction of such Government Agency in the Licensed Territory, other than a patent right, including, without limitation, rights conferred in the U.S. under the Hatch-Waxman Act or the FDA Modernization Act of 1997, or rights similar thereto outside the U.S.

**1.77 "Regulatory Materials"** means regulatory applications, submissions, notifications, communications, correspondence, registrations, Regulatory Approvals and/or other filings made to, received from or otherwise conducted with a Governmental Authority in order to Develop, Manufacture, market, sell or otherwise Commercialize the Product in a particular country, territory or possession. Regulatory Materials include, without limitation, INDs and MAAs.

**1.78 "Reimbursable Expenses"** has the meaning set forth in Section 4.3(c).

**1.79** **"ROW Development Plan"** has the meaning set forth in Section 4.4(a).

**1.80** **"ROW Territory"** means worldwide except the Shared Territory.

**1.81** **"Royalty Term"** means, with respect to a particular Product within a particular country in the Licensed Territory, the period of time beginning upon the date of First Commercial Sale of such Product in such particular country and continuing for so long as such Product is sold in such country.

**1.82** **"Second Source Plan"** has the meaning set forth in Section 7.4(a).

**1.83** **"Shared Territory Development Plan"** has the meaning set forth in Section 4.3(a).

**1.84** **"Shared Territory"** means the United States of America, including its territories and possessions.

**1.85** **"Sole Inventions"** has the meaning set forth in Section 9.1.

**1.86** **"SOPs"** or **"Standard Operating Procedures"** has the meaning set forth in Section 7.5.

**1.87** **"Specifications"** means the procedures, requirements, standards and other items describing and/or relating to the Product (as defined in Section 1.69(a)) set forth in Exhibit A-1 attached hereto.

**1.88** **"Supply Agreement"** has the meaning set forth in Section 7.3.

**1.89** **"Takeda Indemnitees"** has the meaning set forth in Section 11.1.

**1.90** **"Takeda Know-How"** means all Information (a) to the extent related to the Product in the Field that arises from Takeda's activities under this Agreement and is necessary for the Development, Manufacture or Commercialization of such Products in the Field,or (b) that Takeda Controls during the Term that Takeda incorporates in Products and that is necessary for the Development, Manufacture or Commercialization of such Products in the Field. For clarity, Takeda Know-How in each case (a) and (b) excludes (i) any Information contained within the Takeda Patents and (ii) any Information that is not specific to such Products in the Field but generally applicable to Takeda's activities outside of this Agreement.

**1.91** **"Takeda Marks"** means those trademarks and house marks owned by Takeda or its Affiliates and used or intended to be used in connection with the promotion of the Product.

**1.92** **"Takeda Patent"** means (a) any Patent identified on Exhibit B-2 that is Controlled by Takeda as of the Effective Date (it being understood there are no such Patents as of the Effective Date) and any Patent Controlled by Takeda during the Term that Takeda employs in the Development, Manufacture or Commercialization of Products in the Field and is necessary for such Development, Manufacture of Commercialization; (b) any Patent that claims a Sole Invention Controlled by Takeda that is necessary for the Development, Manufacture or

Commercialization of the Products in the Field; or (c) Takeda's interest in any Joint Patent, as well as any patent issuing from an application claiming priority thereto or otherwise continuing therefrom.

**1.93 "Takeda Technology"** means the Takeda Patents and Takeda Know-How.

**1.94 "Take The Lead"** shall mean, with respect to a particular Party, that such Party is primarily responsible for, and has the authority to make, all day-to-day decisions (in accordance with the approved Development Plan and Commercialization Plan) as they relate to such Party's responsibilities, rights and/or obligations hereunder; provided, however, the Parties shall consult with each other with respect to any matters as requested by either Party or as otherwise required by the terms of this Agreement.

**1.95 "Taxes"** means taxes (other than income taxes), duties, tariffs or other governmental charges levied on the sale of Products, including, without limitation, consumption taxes.

**1.96 "Term"** means the term of this Agreement, as determined in accordance with Article 13.

**1.97 "Third Party"** means any entity other than Cell Genesys or Takeda or an Affiliate of either of them.

**1.98 "Third Party Royalties"** has the meaning set forth in Section 8.4(e)(ii).

**1.99 "Upstream Agreements"** has the meaning set forth in Section 2.1(a)(iii).

**1.100 "VITAL Studies"** means, collectively, (i) that certain Phase 3 Clinical Trial conducted by Cell Genesys as of the Effective Date and entitled "A Phase III Randomized, Open-Label Study of CG1940 and CG8711 Versus Docetaxel and Prednisone in Patients With Metastatic Hormone-Refractory Prostate Cancer Who Are Chemotherapy-Naïve," designated internally as VITAL-1 (the "**VITAL-1 Study**"), and (ii) that certain Phase 3 Clinical Trial conducted by Cell Genesys as of the Effective Date and entitled "A Phase 3 Randomized, Open-Label Study of Docetaxel in Combination With CG1940 and CG8711 Versus Docetaxel and Prednisone in Taxane-Naïve Patients With Metastatic Hormone-Refractory Prostate Cancer With Pain," designated internally as VITAL-2 (the "**VITAL-2 Study**").

**1.101 "Withdrawal Notice"** has the meaning set forth in Section 3.5.

## ARTICLE 2

## LICENSES AND EXCLUSIVITY

### 2.1 Licenses to Takeda under Cell Genesys Technology.

#### (a) License and Sublicense.

**(i)** Subject to the terms and conditions of this Agreement and the Upstream Agreements, Cell Genesys hereby grants Takeda an exclusive (even as to Cell Genesys except as provided in Section 2.1(b) below), royalty-bearing license, or sublicense, as the case may be, with the right to sublicense as provided below, under the Cell Genesys Technology, to Develop, use, sell, offer for sale, have sold, Distribute, import and otherwise Commercialize the Product in the Field in the Licensed Territory. Subject to the terms and conditions of this Agreement, the Upstream Agreements, and the Supply Agreement, Cell Genesys hereby grants Takeda a non-exclusive, royalty-bearing license, or sublicense, as the case may be, with the right to sublicense as provided below, under the Cell Genesys Technology, to make and have made the Product for use in the Field in the Licensed Territory.

**(ii)** Takeda acknowledges that, pursuant to the relevant Upstream Agreement, Cell Genesys' license [under U.S. Patents 5,168,062 and 5,385,839 is non-exclusive] and, accordingly, the sublicense granted to Takeda in Section 2.1(a)(i) under such U.S. Patents is [exclusive only with respect to Cell Genesys, and not with respect to its licensor of such patents].

**(iii)** The Cell Genesys Patents sublicensed under Section 2.1(a)(i) and identified on Exhibit B-1 are licensed to Cell Genesys by Third Parties pursuant to its license agreements with such Third Party licensors listed in Exhibit B-3 (the "**Upstream Agreements**"). Takeda acknowledges and agrees that its sublicense rights to such patents under this Agreement are at all times subject to the applicable terms of the Upstream Agreements, current copies of which have been provided to Takeda as of the Effective Date. Takeda covenants (i) to comply and cause its sublicensees to comply with the terms of the Upstream Agreements as applicable to sublicensees; and (ii) not to take or fail to take any action that would constitute or be likely to result in a breach of any Upstream Agreements. Takeda shall be liable to Cell Genesys for the acts or omissions of its sublicensees and any breach of an applicable provision of an Upstream Agreement by a sublicensee of Takeda shall be deemed to be a breach of this Agreement by Takeda. Subject to the provisions of the following sentence, Cell Genesys covenants (i) to comply and cause any Third Party sublicensees to comply with the terms of the Upstream Agreements as applicable to sublicencees, (ii) not to take or fail to take any action that would constitute or be likely to result in a breach of any Upstream Agreements, and (iii) not to amend the Upstream Agreements without Takeda's prior written consent; provided, however, Takeda's prior written consent shall not be required for any amendment to the Upstream Agreements that relate exclusively to any rights granted to Cell Genesys thereunder that are not sublicensed to Takeda under this Agreement. Cell Genesys shall provide prior notice to Takeda of any amendment of the Upstream Agreements and shall not terminate in whole any Upstream Agreement without Takeda's prior written consent. Cell Genesys shall be liable to Takeda for the acts or omission of its sublicensees and any breach of an applicable provision of an Upstream Agreement by a sublicensee of Cell Genesys shall be deemed to be a breach of this Agreement by Cell Genesys to the extent such breach affects the rights granted to Takeda under this Agreement.

**(b) Cell Genesys Retained Rights**. Notwithstanding the rights granted to Takeda in Section 2.1(a) and without limiting the generality of Section 2.4, Cell Genesys retains the following: (i) the right to conduct or have conducted the Development and Commercial activities expressly permitted to be conducted by Cell Genesys under this Agreement, including the conduct of the VITAL Studies, Currently Ongoing Studies and any Additional Studies

designated to be performed by Cell Genesys under Section 4.3(b)(iii) of this Agreement; (ii) rights to Manufacture or have Manufactured Products, anywhere in the Licensed Territory, including formulation and processing of the Product; and (iii) all rights to the Cell Genesys Technology outside the Field subject to [Cell Genesys' option with respect to Takeda's interest in the Takeda Patents] under Section 2.2(b) and 13.5(f).

**(c) Sublicense Rights**. Subject to the terms of the applicable Upstream Agreements, Takeda shall have the right to sublicense the rights set forth in Section 2.1(a) subject to Cell Genesys' written consent, which shall not be unreasonably withheld, conditioned or delayed, except: (i) with respect to [activities in the Shared Territory, Takeda may sublicense such rights to an Affiliate without such consent], and (ii) with respect to [activities in the ROW Territory, Takeda may sublicense such rights to an Affiliate or Third Party without such consent]. Promptly after the execution of any sublicense agreement, Takeda shall notify Cell Genesys and, if requested in writing by Cell Genesys, provide Cell Genesys with a copy of such agreement for the purpose of identifying the sublicensed territory, the sublicensee and the scope of rights and intellectual property rights granted; provided, that any other information Takeda reasonably deems to be confidential may be redacted, to the extent permitted by any applicable Upstream Agreement. Takeda hereby covenants that it will include in all agreements granting sublicenses under the rights granted in Section 2.1(a) provisions consistent with the terms of this Agreement and the applicable Upstream Agreements as applicable to a sublicensee.

### 2.2 License to Cell Genesys under Takeda Technology

**(a)** Subject to the terms and conditions of this Agreement, Takeda hereby grants to Cell Genesys a non-exclusive, royalty-free, license (with the right to sublicense) in the Field under the Takeda Technology to Develop, use, make, and have made the Product in the Licensed Territory pursuant to the terms of this Agreement and the Supply Agreement.

**(b)** Takeda hereby grants to Cell Genesys [an exclusive option to obtain, at Cell Genesys' option, an exclusive or non-exclusive, worldwide, royalty-bearing license under Takeda's interest in any Takeda Patents (solely to the extent such Takeda Patents were generated by activities under this Agreement) that are generally applicable to GVAX products, such license limited to research, develop, make, have made, use, offer for sale, sell and import GVAX products outside the Field.] For clarity, subject to the previous sentence, Takeda shall retain all of its rights under Joint Patents as applicable to non-GVAX products outside the Field, and Cell Genesys shall retain all of its rights under Joint Patents. [On a Takeda Patent-by-Takeda Patent basis, Cell Genesys may exercise such option at any time prior to one (1) year after the grant of any such Takeda Patent by written notice to Takeda, and the Parties will thereafter negotiate the terms of a license agreement pursuant to Section 8.10].

### 2.3 Negative Covenants.

**(a) Mutual Covenants.** Each Party covenants that it will not use or practice any of the other Party's intellectual property rights licensed to it under this Article 2 except for the purposes expressly permitted in the applicable license grant.

**(b) Takeda Covenant Regarding Joint Patents**. During the period that Joint Patents are in force, Takeda hereby covenants not to practice or grant licenses under the Joint Patents to [directly or indirectly sell, offer for sale, have sold, import and otherwise Commercialize any pharmaceutical product which directly competes with a GVAX product then being sold by or on behalf of Cell Genesys], except as may otherwise be agreed in writing by Cell Genesys. [In consideration for such negative covenant, any license negotiated pursuant to Section 2.2(b) shall include a royalty or such other reasonable compensation payable to Takeda with respect to Takeda's interest in the Joint Patents.] Nothing contained in this Section 2.3(b) is intended to [preclude Takeda from selling, offering for sale, having sold, importing or otherwise Commercializing any pharmaceutical product which may be indicated for the same therapeutic area as such GVAX product as long as such Takeda product is not within the scope of GVAX set forth in Section 1.37].

**2.4 No Implied Licenses**. Except as explicitly set forth in this Agreement, neither Party grants any license, express or implied, under its intellectual property rights to the other Party.

## ARTICLE 3

## OVERVIEW; MANAGEMENT

### 3.1 Joint Steering Committee.

**(a) Formation and Role**. The Parties agree to establish and convene a Joint Steering Committee (or "**JSC**") for the overall coordination and oversight of the Parties' activities under this Agreement, promptly after the Effective Date. Each Party shall have an equal number of representatives on the JSC. The JSC shall operate by the procedures set forth in Section 3.4. Except as otherwise provided in Section 14.3(b) and subject to Section 14.2(b), the role of the Joint Steering Committee shall be:

**(i)** For the Shared Territory, (1) to review, coordinate, discuss and approve the overall strategy for the Development, Manufacture, and Regulatory Approval (including the initial approval and any supplements and expansions thereof) of Product and (2) to review and discuss the overall strategy for the Commercialization of the Product subject to subsection (iv) below;

**(ii)** For the ROW Territory, to review and discuss the overall strategy for the Development, Manufacture, Regulatory Approval (including the initial approval and any supplements and expansions thereof) and Commercialization of Product;

**(iii)** to review, discuss and approve the Shared Territory Development Plan on or before December 1 of each calendar year, and any proposed amendments or revisions to the such plan;

**(iv)** to review, discuss and approve the Commercialization Plan, and any proposed amendments or revisions to such plan provided Cell Genesys has exercised the Co-Promotion Option;

**(v)** to resolve any disputes arising within the JDC and JCC; and

**(vi)** to establish such subcommittees, including without limitation the regulatory working group as provided in Section 5.3 and the Publication Team as provided in Section 6.11, and to perform such other functions as appropriate to further the purposes of this Agreement, as mutually agreed by the Parties in writing.

**(b) JSC Decisions and Actions**. Actions to be taken by the Joint Steering Committee shall be taken only following unanimous vote, with each Party having one (1) vote. Except as otherwise provided in Section 14.3(b), if the Joint Steering Committee fails to reach unanimous agreement on a matter before it for decision for a period in excess of fifteen (15) days from the date first presented to the JSC in writing, the matter shall be submitted immediately to a senior executive officer designated in writing by each Party (a "**Designated Executive**") for resolution in accordance with the decision-making procedures described in Section 14.2, including the specific decision-making rights of each Party as described in such section.

### 3.2 Joint Development Committee.

**(a) Formation and Role**. The Parties also agree to establish a Joint Development Committee (or "**JDC**") which will monitor and coordinate communication and operations regarding the Parties' efforts with respect to the Development, Manufacture, and Regulatory Approval of the Product in the Field and in the Licensed Territory. Each Party shall have an equal number of representatives on the Joint Development Committee. The Joint Development Committee shall operate by the procedures set forth in Section 3.4. The role of the Joint Development Committee shall be:

**(i)** to facilitate the exchange of Information between the Parties under this Agreement with respect to their Product-related activities (including activities conducted in the Shared Territory and the ROW Territory), including as and to the extent necessary for each Party to perform its obligations under this Agreement;

**(ii)** to review and comment on the Shared Territory Development Plan and all amendments and updates thereto, and to submit such plan to the JSC for approval (it being understood that the JDC shall submit such plan with sufficient time for the JSC to review and approve such plan on or before December 1 of each calendar year);

**(iii)** to review and discuss the ROW Territory Development Plan and all amendments and updates thereto; and

**(iv)** to establish such working teams or subcommittees and to perform such other functions as appropriate to further the purposes of this Agreement, as determined by the Parties in writing.

**(b) JDC Decisions and Actions**. Except as expressly provided in this Section 3.2, actions to be taken by the JDC shall only be taken following unanimous vote, with each Party having one (1) vote. Except as otherwise provided in Section 14.3(b), if the Joint Development Committee fails to reach unanimous agreement on a matter before it for decision for a period in

excess of ten (10) days from the date first presented to the JDC in writing, the matter shall be referred immediately to the Joint Steering Committee.

### 3.3 Joint Commercial Committee.

**(a) Formation and Role.** The Parties also agree to establish a Joint Commercial Committee (or "**JCC**") which will monitor and coordinate communication and operations regarding the Parties' efforts with respect to the Commercialization of the Product in the Field and in the Licensed Territory. Each Party shall have an equal number of representatives on the Joint Commercial Committee. The Joint Commercial Committee shall operate by the procedures set forth in Section 3.4. The role of the Joint Commercial Committee shall be:

**(i)** if Cell Genesys has exercised its Co-Promotion Option, to review and approve the Commercialization Plan for the Shared Territory and all updates thereto (including market research and other commercial data);

**(ii)** if Cell Genesys has not exercised its Co-Promotion Option, to review and comment on the Commercialization Plan for the Shared Territory and all updates thereto;

**(iii)** to review and comment on Takeda's Commercialization activities for the Product in the ROW Territory;

**(iv)** to review and comment on the distribution channel design and reimbursement strategy for the Commercialization of Products in the Licensed Territory; and

**(v)** to establish such working teams or subcommittees and to perform such other functions as appropriate to further the purposes of this Agreement, as determined by the Parties in writing.

**(b) JCC Decisions and Actions.** The JCC will have express decision-making authority as described herein for the Shared Territory only if Cell Genesys has exercised its Co-Promotion Option. Except as expressly provided in this Section 3.3, in such event of exercise, actions to be taken by the JCC shall only be taken following unanimous vote, with each Party having one (1) vote. Except as otherwise provided in Section 14.3(b), if the Joint Commercial Committee fails to reach unanimous agreement on a matter before it for decision for a period in excess of ten (10) days from the date first presented to the JCC in writing, then the matter shall be referred immediately to the JSC for resolution. If Cell Genesys has not exercised its Co-Promotion Option, then the JCC will be advisory in nature only, and the foregoing shall not apply.

### 3.4 Committee Membership and Procedures.

**(a) Membership.** Cell Genesys and Takeda shall each designate an equal number of representatives to serve on each of the JSC, JDC and JCC (each, a "**Committee**") by written notices to the other Party. Initially, each Party shall designate three (3) such representatives. Each Committee may elect to vary the number of representatives from time to time during the Term. Either Party may designate substitutes for its Committee representatives if one (1) or more of such Party's designated representatives is unable to be present at a meeting.

From time to time each Party may replace its Committee representatives by written notice to the other Party specifying the prior representative(s) and their replacement(s). Any such substitutes or replacements shall be designated consistent with the following principles: at least one (1) representative shall have appropriate expertise in the clinical development of pharmaceutical products; provided, that each Committee may vary the expertise required for the representatives of each Party as it deems appropriate as the Parties gain experience with the Product. Each Committee will have a chairperson, to be designated as described below. The chairperson shall be responsible for (i) calling meetings, and (ii) preparing and circulating an agenda for the upcoming meeting, but shall have no special authority over the other members of the Committee, and shall have no additional voting rights. The alliance managers described in Section 3.6 shall be responsible for preparing and issuing minutes of each JSC meeting within thirty (30) days thereafter. Such minutes shall not be finalized until each Committee representative reviews and approves such minutes in writing; provided that any minutes shall be deemed approved unless a member of the JSC objects to the accuracy of such minutes within fifteen (15) days after the circulation of the minutes by the chairperson. The chairpersons of other subcommittees will be responsible for generating minutes from their respective meetings.

**(b) Chairperson.**

**(i)** The chairperson of the JSC shall be appointed each twelve (12) months, with Cell Genesys appointing the initial chairperson. On January 1 of each year after the Effective Date, the Parties shall rotate designation of the chairperson for the JSC for the commencing year.

**(ii)** The initial chairperson of the JDC will be designated by Cell Genesys. Promptly following submission of the first MAA for a Product in the Licensed Territory, Takeda will be entitled to replace the chairperson with a Takeda representative to serve for at least twelve (12) months after which time Cell Genesys shall be entitled to designate the chairperson in accordance with the terms of subsection (b)(i).

**(iii)** The chairperson of the JCC will be designated by Takeda.

**(c) Meetings.** Meetings of a Committee shall be effective only if at least two (2) representatives of each Party are present or participating. A Committee may meet either (a) in person at either Party's facilities or at such locations as the Parties may otherwise agree; or (b) by audio or video teleconference. With the prior consent of the other Party's representatives (such consent not to be unreasonably withheld or delayed), each Party may invite non-members to participate in the discussions and meetings of a Committee, provided that such participants shall have no voting rights or powers and shall be subject to the confidentiality provisions set forth in Article 12. Additional meetings of a Committee may be held with the consent of each Party, as required under this Agreement, or to resolve any dispute referred to it and neither Party will unreasonably withhold or delay its consent to hold such an additional meeting (and in the case of any dispute referred to the JSC, such meeting shall be held within five (5) business days following referral to the JSC, or as soon as reasonably possible). Each Party shall be responsible for all of its own expenses incurred in connection with participating in the Committees including expenses associated with an initial alliance kick-off meeting.

**(i)** The JSC shall hold at least (3) meetings per year, or as otherwise agreed to by the Parties, with at least one (1) of such meetings being held in person.

**(ii)** The JDC and JCC shall each hold a meeting at least every other month, or as otherwise agreed to by the Parties. In addition, each Party shall designate a member of the JCC to participate in JDC meetings and a member of the JDC to participate in JCC meetings. Unless otherwise agreed to by the Parties, the JDC and JCC shall hold at least four joint meetings each year to facilitate alignment and communication.

**3.5 Withdrawal from Committees**. At any time during the Term and for any reason, Cell Genesys shall have the right to withdraw from participation in the Committees upon written notice to Takeda, which notice shall be effective immediately upon receipt ("**Withdrawal Notice**"). Following the issuance of a Withdrawal Notice and subject to this Section 3.5, Cell Genesys' representatives to the Committees shall not participate in any meetings of the Committees, nor shall Cell Genesys have any right to vote on decisions within the authority of the Committees. If, at any time following the second anniversary of the issuance of a Withdrawal Notice, Cell Genesys wishes to resume participating in the Committees, Cell Genesys shall provide Takeda with ninety (90) days prior written notice and, following such notice period, Cell Genesys representatives to the Committees shall be entitled to attend any subsequent meeting of the Committees and to participate in the activities of, and decision-making by, the Committees as provided in this Article 3 as if a Withdrawal Notice had not been issued by Cell Genesys pursuant to this Section 3.5. Following Cell Genesys' issuance of a Withdrawal Notice pursuant to this Section 3.5, unless and until Cell Genesys resumes participation in the Committees in accordance with this Section 3.5: (i) all meetings of the Committees shall be held at Takeda's facilities; (ii) Takeda shall have the right to make the final decision on all matters within the scope of authority of the Committees; and (iii) Cell Genesys shall have the right to continue to receive all reports and materials provided to the Committees hereunder as well as reasonable advance notice of any pending Committee decisions relating to the matters described in Section 14.2(b)(i), but shall not have the right to approve the minutes for any Committee meeting held after Cell Genesys' issuance of a Withdrawal Notice. For clarity, the withdrawal by Cell Genesys under this Section 3.5 shall only limit Cell Genesys' obligations under this Article 3 with respect to participation in the Committees.

**3.6 Alliance Managers**. Promptly following the Effective Date, each Party shall designate in writing an individual to facilitate communication and coordination of the Parties' activities under this Agreement relating to Products.

**3.7 Authority**. The JSC, JDC and JCC shall each perform its responsibilities under this Agreement based on the principles of prompt and diligent Development, Manufacture and Commercialization of Products in the Licensed Territory, consistent with good pharmaceutical practices and commercially reasonable consideration of the optimal balance of maximizing long-term profits derived from the sale of Products in the Licensed Territory in the context of the estimated costs for Development of such Products in the Licensed Territory. The Committees shall each have only the powers assigned expressly to it in this Article 3 and elsewhere in this Agreement, and shall not have any power to amend, modify or waive compliance with this Agreement.

**3.8 Collaboration Guidelines**. Subject to the terms of this Agreement, the activities and resources of each Party shall be managed by such Party, acting independently and in its individual capacity. The relationship between Cell Genesys and Takeda is that of independent contractors and neither Party shall have the power to bind or obligate the other Party in any manner, other than as may be expressly set forth in this Agreement.

**3.9 Diligence**. Takeda shall use Diligent Efforts to Develop, to seek Regulatory Approval for and Commercialize Products for use in the Field in accordance with the terms of this Agreement and for (i) the Shared Territory in accordance with the Shared Territory Development Plan and (ii) the ROW Territory in accordance with the ROW Development Plan. Notwithstanding the foregoing sentence, Takeda's obligation to use Diligent Efforts shall not apply to the extent of any delay or failure by or on behalf of Cell Genesys to supply Products or to timely transfer manufacturing technology to Takeda or its designee. Cell Genesys shall use Diligent Efforts to conduct, in accordance with the terms of this Agreement, the (I) Development (including regulatory activities related to MAAs held by Cell Genesys), Manufacturing and Commercialization activities to be performed by it under this Agreement for the Shared Territory in accordance with the Shared Territory Development Plan and (II) Development (including regulatory activities related to MAAs held by Cell Genesys) and Manufacturing activities to be performed by it under this Agreement for the ROW Territory in accordance with the ROW Development Plan.

## ARTICLE 4

## PRODUCT DEVELOPMENT

**4.1 Overview of Product Development**. The Parties desire and intend to collaborate with respect to the Development of the Product in the Licensed Territory in the Field, as and to the extent set forth in this Agreement. The general allocation of responsibilities for conducting Development of the Product shall be as follows: (1) Cell Genesys shall be responsible for performing the VITAL Studies and the Currently Ongoing Studies; and (2) except as provided in the following sentence, the JDC will allocate responsibility for the performance of any Additional Studies between the Parties. The JCC will allocate between the Parties responsibility for the performance of those Additional Studies which are of the type that typically fall within the oversight of Takeda's commercial functions, including, without limitation, certain Phase 4 Clinical Studies, investigator-sponsored trials and reimbursement studies.

**4.2 Principles of Product Development**. Each Party's Development of the Product in the Field for the Licensed Territory shall be conducted in a manner consistent with the following principles: (1) seeking Regulatory Approval that includes the appropriate label for such Product in light of the clinical data, and (2) obtaining Regulatory Approval for such Product consistent with the preceding clause and in a timely manner.

**4.3 Shared Territory**.

**(a) Shared Territory Development Plan**.

(i) **General**. The Parties shall collaboratively conduct the Development of the Product for the Shared Territory pursuant to a mutually agreed written development plan (the "**Shared Territory Development Plan**"). The Shared Territory Development Plan will contain the following information, to the extent such information is available:

(1) scope and target timelines for all Development and Manufacturing activities in reasonable detail as agreed by the Parties supporting Regulatory Approvals for the Product in the Field in the Shared Territory, including the VITAL Studies, the Currently Ongoing Studies, and any Additional Studies for the Shared Territory;

(2) calendar year and fiscal year budgets which shall include a three (3) year rolling budget for Development and Manufacturing activities (including a detailed binding budget for the first year of each such calendar year and fiscal year budgets and a non-binding forecast for subsequent two (2) years based on the then-current Shared Territory Development Plan; and

(3) plans and timeline for preparing the necessary Development and Manufacturing Regulatory Materials in support of obtaining Regulatory Approval in the Shared Territory for the first indication and any label expansion.

(ii) **Initial Shared Territory Development Plan**. The Parties have agreed upon an initial Shared Territory Development Plan and associated calendar year budget, which is attached hereto as Exhibit C. The Parties anticipate revising such Shared Territory Development Plan following execution of this Agreement in accordance with then-current information regarding Product Development and the terms and conditions of this Agreement.

(iii) **Updates to Shared Territory Development Plan**. On at least an annual basis and in the timeframe provided in Section 3.1(a)(iii), commencing in 2008, the JDC shall update and amend, as appropriate, the then-current Shared Territory Development Plan. The JDC shall submit all updates and amendments to the Shared Territory Development Plan approved by it to the JSC for review and approval. Once approved by the JSC, each updated or amended Shared Territory Development Plan shall become effective and supersede the previous Shared Territory Development Plan as of the date of such approval or at such other time as decided by the JDC.

(b) **Conduct and Cost of Studies**.

(i) **VITAL Studies**. The Parties intend and agree that any and all VITAL Studies shall be conducted by Cell Genesys, in collaboration and consultation with Takeda and under the direction of the JDC. Cell Genesys shall bear all Internal FTE Costs incurred after the Effective Date in connection with the performance and conduct of the VITAL Studies in accordance with the protocols (or any protocol amendments made as of the Effective Date) for such studies in effect as of the Effective Date. Takeda will be responsible for reimbursing all Out-of-Pocket Costs and Clinical Supply Costs incurred after the Effective Date in connection with the performance and conduct of the VITAL Studies. A calendar year budget for the VITAL Studies will be included in the Shared Territory Development Plan. Cell Genesys

shall not exceed such budget for the VITAL Studies by more than [five percent (5%)] without the prior written approval of the JDC. Notwithstanding anything to the contrary in this Agreement, Takeda shall not be obligated to reimburse, and Cell Genesys shall not be required to conduct any activity that would require Cell Genesys to incur, on an annualized basis, any Out-of-Pocket Costs or Clinical Supply Costs for the VITAL Studies that exceed such budget for the VITAL Studies by more than [ten percent (10%)] in the aggregate. Subject to the provisions in Section 8.4(d), any reimbursement due Cell Genesys pursuant to this Section 4.3(b)(i) will be made pursuant to the procedures described in Section 4.3(c) below. If a decision is made in consultation with the JDC to increase the sample size for the VITAL-2 Study, Cell Genesys agrees to obtain, in consultation with Takeda, agreement from the applicable Regulatory Authority prior to amending the current study protocol. For the avoidance of doubt, any amendments or supplements to the protocols for the VITAL-2 Studies, or other continuations or extensions thereof, made after the Effective Date, shall be (1) considered Additional Studies and subject to Sections 4.3(b)(iii) and 14.2(b)(ii) and (2) the reimbursement by Takeda of costs related thereto shall be credited against royalties in accordance with Section 8.4(d).

**(ii) Currently Ongoing Studies**. The Parties intend and agree that any and all Currently Ongoing Studies shall be conducted by Cell Genesys at its discretion, in collaboration and consultation with Takeda and in consultation with the JDC. Cell Genesys shall bear all costs incurred in connection with the performance and conduct of the Currently Ongoing Studies. For the avoidance of doubt, any amendments [(excluding the amendment pending as of the Effective Date to the clinical study designated G-0016: "A Phase 1 Dose Escalation Trial of MDX-010 in Combination with CG1940 and CG8711 in Patients with Metastatic Hormone-Refractory Prostate Cancer")] or supplements to the protocols for such Currently Ongoing Studies, or other continuations or extensions thereof, made after the Effective Date, shall be considered Additional Studies and subject to Sections 4.3(b)(iii) and 14.2(b)(ii).

**(iii) Additional Studies**. The Parties understand and recognize that one or more Additional Studies may be conducted for the Shared Territory after the Effective Date. In such event, the Parties, through the JDC, shall meet and discuss which Party shall be responsible for the conduct of such Additional Studies and the associated timelines and budget therefor, and shall update the Shared Territory Development Plan accordingly. Takeda shall bear all costs incurred by either Party in connection with the performance and conduct of the Additional Studies, including any Internal FTE Costs, Out-of-Pocket Costs and Clinical Supply Costs for such studies. A calendar year budget for the Additional Studies in the Shared Territory will be included in the Shared Territory Development Plan. Cell Genesys shall not exceed the amount allocated in such budget for the Additional Studies performed by Cell Genesys by more than [five percent (5%)] without the prior written approval of the JDC. Notwithstanding anything to the contrary in this Agreement, Takeda shall not be obligated to reimburse, and Cell Genesys shall not be required to conduct any activities that would require Cell Genesys to incur, on an annualized basis, any Internal FTE Costs, Out-of-Pocket Costs or Clinical Supply Costs for the Additional Studies that exceed the amount allocated in the then-current budget for the Additional Studies performed by Cell Genesys by more than [ten percent (10%)] in the aggregate. Subject to the provisions in Section 8.4(d), any reimbursement due Cell Genesys pursuant to this Section 4.3(b)(iii) will be made pursuant to the procedures described in Section 4.3(c) below.

**(iv) Post-Approval Commitments.** Cell Genesys agrees to provide Takeda technical assistance in the form of personnel to support the conduct of studies in regards to the manufacturing, nonclinical or clinical area that may be required to meet post-approval commitments in the Shared Territory. Takeda shall bear the cost incurred by either Party in connection with the performance and conduct of post-approval commitments, including any Internal FTE Costs, Out-of-Pocket Cost and Clinical Supply Costs for such studies.

**(v) Clinical Study Registry.** Cell Genesys agrees to register in the FDA clinical trial registry (clinicaltrials.gov) the VITAL Studies, Currently Ongoing Studies, and any Additional Study conducted under an IND filed by Cell Genesys and as required by applicable Law. Cell Genesys further agrees to allow Takeda to post the clinical trial results of these studies and to link the registry to the clinical results of all studies that are the basis for the efficacy claims in the Shared Territory, and the results of any additional studies that are conducted post filing or approval that provide additional information that is relevant to the use of the Product, provided that, prior to the first Regulatory Approval in both the U.S. and the European Union, in each case Cell Genesys is provided with such results in advance and consents in writing to such posting, not to be unreasonably withheld, conditioned or delayed. Takeda shall be responsible for registering in the FDA clinical trial registry (clinicaltrials.gov) and posting the results of all studies conducted under an IND filed by Takeda for Products in the Field.

**(vi) Performance.** Each Party agrees to conduct the VITAL Studies, Currently Ongoing Studies, and any Additional Studies allocated to it as described in this Section 4.3(b) in accordance with the Shared Territory Development Plan. Cell Genesys and Takeda each shall provide the JDC with annual reports detailing its Development activities under the Shared Territory Development Plan and the results thereof.

**(c) Reimbursement Procedures.** Cell Genesys shall calculate and maintain records of all relevant reimbursable expenses (including Internal FTE Costs, Out-of-Pocket Costs and Clinical Supply Costs) incurred by it for the Development of the Product (collectively, the "**Reimbursable Expenses**"), in accordance with procedures to be agreed upon between the Parties and the following:

**(i)** Within twenty (20) business days following the end of each calendar month, Cell Genesys shall submit to Takeda a written report setting forth in reasonable detail the Reimbursable Expenses it has incurred in such calendar month. Within ten (10) business days following its receipt of such report, Takeda shall confirm in writing its acceptance of the calculation of Reimbursable Expenses set forth therein.

**(ii)** Within thirty (30) business days following the end of the months of March, June and September and within forty five (45) business days following the end of the month of December during each calendar year, Cell Genesys shall submit to Takeda the report specified in subsection (i) above together with an invoice for all Reimbursable Expenses incurred during such calendar quarter. Within ten (10) business days following its receipt of such report, Takeda shall confirm in writing its acceptance or rejection of the calculation of Reimbursable Expenses set forth in the report. Takeda shall pay the portion of each invoice corresponding to an accepted calculation of the amount of Reimbursable Expenses by wire transfer in accordance

with the terms of Section 8.7 within five (5) business days following receipt of written acceptance of the calculation.

**(iii)** In the event of a dispute regarding the amount of Reimbursable Expenses set forth in any monthly report, any amounts not in dispute shall be paid in accordance with the applicable invoice and Takeda shall provide written notice without undue delay after receipt of the written report in question to Cell Genesys, specifying such dispute and explaining the basis of the dispute. The Parties shall promptly thereafter meet and negotiate in good faith a resolution to such dispute and, promptly upon resolution of such dispute, Takeda shall make the agreed-upon payment. If such dispute is not resolved within forty-five (45) days after delivery of a notice of dispute by Takeda, then Takeda may audit Cell Genesys in accordance with the provisions of Section 4.3(d).

**(d) Records; Audits**. Cell Genesys will maintain complete and accurate records in sufficient detail to permit Takeda to confirm the accuracy of the Reimbursable Expenses under this Agreement. Upon reasonable prior notice, such records shall be available during regular business hours for a period of three (3) years from the end of the calendar year to which they pertain for examination at the expense of Takeda, and not more often than once each calendar year, by an independent certified public accountant selected by Takeda and reasonably acceptable to Cell Genesys, for the sole purpose of verifying the accuracy of the financial reports furnished by Cell Genesys pursuant to this Agreement. Any such auditor shall not disclose Cell Genesys' Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by Cell Genesys or the amount of Reimbursable Expenses due Cell Genesys under this Agreement. Any amounts shown to be owed but unpaid shall be paid within thirty (30) days from the accountant's report, plus interest (as set forth in Section 8.7) from the original due date. Any amounts shown to have been overpaid shall be refunded within thirty (30) days from the accountant's report. Takeda shall bear the full cost of such audit unless such audit discloses an overstatement of Reimbursable Expenses of more than [five percent (5%)] of the amount due, in which case Cell Genesys shall bear the full cost of such audit.

### 4.4 ROW Territory.

**(a) General; ROW Development Plan**. Takeda shall conduct the Development of the Product for the ROW Territory, in collaboration and consultation with Cell Genesys through the JDC subject to the terms and conditions of this Agreement, and pursuant to a written development plan (the **"ROW Development Plan"**). The ROW Development Plan will be summary in nature, but will include all Development and Manufacturing activities anticipated to be required for obtaining Regulatory Approval in the ROW Territory and timelines regarding such activities. The ROW Development Plan shall also specify the plans and timeline for preparing the necessary Regulatory Materials and for obtaining Regulatory Approval in the ROW Territory for the first indication and any label expansion. On at least an annual basis (no later than December 1 of each calendar year, commencing in 2008), Takeda shall update and amend, as appropriate, the then-current ROW Development Plan and shall submit such updates and/or amendments for review and comment by the JDC. Takeda shall review and consider all comments to the ROW Development Plan from the JDC or JSC in good faith. The ROW Development Plan shall not require the approval of the JDC or the JSC, but this shall not excuse

Takeda from otherwise meeting its obligations with respect to the Development of the Product in the ROW Territory as provided in this Agreement. Except for the VITAL Studies conducted by Cell Genesys or as Cell Genesys may agree at the JSC, Takeda will be responsible, at its expense for conducting all studies necessary or desirable for any Regulatory Approvals in the ROW Territory pursuant to the ROW Development Plan.

**(b) Additional Studies**. The Parties intend and agree that any and all Additional Studies in the ROW Territory shall be conducted by Takeda, in collaboration and consultation with Cell Genesys and in consultation with the JDC. Takeda shall bear all of its costs incurred in connection with the performance and conduct of such Additional Studies.

**(c) Post-Approval Commitments.** Cell Genesys agrees to provide Takeda technical assistance in the form of personnel to support the conduct of studies in regards to the manufacturing, nonclinical or clinical area that may be required to meet post-approval commitments in the ROW Territory. Takeda shall bear the cost incurred by either Party in connection with the performance and conduct of post-approval commitments, including any Internal FTE Costs, Out-of-Pocket Cost and Clinical Supply Costs for such studies.

**(d) Performance.** Takeda agrees to conduct the Additional Studies allocated to it as described in this Section 4.4 above in accordance with the ROW Development Plan and under the direction of the JDC and JSC Takeda shall provide the JDC with annual reports detailing its Development activities for the ROW Territory and the results thereof.

**4.5 Cooperation; Compliance with Laws.** Each Party shall provide financial and other support for the Development of the Product as necessary to achieve the objectives of this Agreement in accordance with the applicable Development Plan. Each Party shall conduct its activities under this Agreement in good scientific manner and in compliance in all material respects with all applicable Laws, including without limitation applicable national and international (*e.g.*, ICH, GCP, GLP, and GMP) guidelines.

**4.6 Records, Reports and Information**. Each Party shall maintain complete, current and accurate records of all Development and Manufacturing activities conducted by it hereunder, and all data and other Information resulting from or relating to such activities, including but not limited to the investigator brochure, IND annual report, and any safety plans established during Development. Such records shall fully and properly reflect all work done and results achieved in the performance of the Development or Manufacturing activities in good scientific manner appropriate for regulatory purposes. Each Party shall document all Non-Clinical Studies and clinical trials in formal written study reports according to applicable national and international (*e.g.*, ICH, GCP, GLP, and GMP) guidelines. Each Party shall have the right to review such records maintained by the other Party at reasonable times, upon written request, which shall not exceed once a year.

**4.7 Data Exchange and Use.** Each Party shall promptly provide the other Party with copies of all final reports with respect to the conduct of any Development of the Product in the Field and with access to, upon request of a Party, all data with respect to the conduct of any Development of the Product in the Field, in each case as such data and reports become available to the Party performing the corresponding studies. Takeda acknowledges and agrees that Cell

Genesys may use and license data related to the VITAL Studies, Currently Ongoing Studies, Product mechanism of action, Product safety information generated pursuant to the Development hereunder with Cell Genesys' Affiliates and Third Party licensees and that such Affiliates and licensees may use, free of charge, any such data solely for developing and commercializing GVAX products outside the Field, including associated regulatory activities, subject to the rights granted to Takeda under this Agreement for the Product in the Field. Cell Genesys shall have the right, with respect to any other data generated by or on behalf of Takeda or its Affiliates with respect to Additional Studies conducted hereunder (the **"Other Collaboration Data"**), to use and license Other Collaboration Data to Cell Genesys' Affiliates and Third Party licensees solely for their use for developing and commercializing GVAX products outside the Field, including associated regulatory activities, [subject to the payment of a royalty for such Other Collaboration Data pursuant to Section 8.10] and subject to the rights granted to Takeda under this Agreement for the Product in the Field. All data and reports disclosed by one Party to the other under this Agreement shall be deemed Confidential Information of the disclosing Party, subject to the permitted uses and disclosures described in this Section 4.7 and disclosure to any Regulatory Authority in connection with a Party's obligations under Article 5.

**4.8 Designation of Additional Products**. If either Party desires to commence development of an Additional Product in the Field, then such Party shall notify the JSC in writing and provide a draft development plan for such Additional Product in the Shared Territory to the JSC. The JSC shall consider such development plan in good faith in accordance with the terms of this Agreement. Upon approval by the JSC, the Parties shall either amend the then-current Development plans and Commercialization Plan to include such Additional Product or prepare separate plans to include terms relating to such Additional Product. The Parties shall determine a reasonable process for the timely delivery of Information regarding any potential Additional Products by each Party to the JDC and/or JSC.

## ARTICLE 5

## REGULATORY MATTERS

**5.1 Initial Data Transfer**. Within sixty (60) days after the Effective Date, Cell Genesys shall make available to Takeda copies of all Regulatory Materials of Cell Genesys generated as of the Effective Date and relating to the use of the Product (as defined in Section 1.69(a)) in the Field. Within ninety (90) days after execution of this Agreement, Cell Genesys shall deliver to Takeda copies of the study reports from Phase 1 Clinical Trials and Phase 2 Clinical Trials completed as of the Effective Date that are Controlled by Cell Genesys (to the extent not previously provided to Takeda), as such reports become available to Cell Genesys, and to the extent that they relate to the use of the Product in the Field.

**5.2 Preparation of Regulatory Materials**.

**(a) Shared Territory**.

**(i)** Cell Genesys shall retain ownership of [BB-IND 9678] and shall be primarily responsible for maintaining such IND and all Regulatory Materials associated therewith, and including without limitation the activities described in Section 5.7 and including

to support the initial MAA for the Product described in Section 1.69(a) in the Shared Territory. Takeda shall have the right to reference such IND as and to the extent described in Section 5.6. Upon written request from Takeda, Cell Genesys shall request, with respect to such initial MAA, a pre-submission meeting with the FDA and Takeda shall have the right to participate and play a leadership role in such meeting. Cell Genesys shall have the right to transfer ownership of [BB-IND 9678] to Takeda at any time upon not less than sixty (60) days prior written notification. Cell Genesys shall not terminate or inactivate such IND without prior consultation with and approval of Takeda. Takeda shall have the right to open a new IND, if necessary or desirable, for Development of other indications. Cell Genesys shall have the right to reference such IND as and to the extent described in Section 5.6.

**(ii)** Takeda shall Take the Lead and be the responsible party, in consultation with Cell Genesys, for preparing, filing and holding the MAA in the Shared Territory and any and all Regulatory Materials (except as provided in Section 5.2(a)(i)) in the Shared Territory associated with any MAA for the Product or amendments or supplements thereto. Such Regulatory Materials and related Regulatory Approvals shall be owned solely by Takeda and held in its name, subject to the terms of Sections 5.2(a)(iv) below and Cell Genesys' rights under this Agreement (other than promotional materials, which shall be owned solely by Takeda). Takeda shall be primarily responsible, in consultation with Cell Genesys, for performing all activities required by such Regulatory Authority with respect to (1) maintaining the MAA, maintaining the Regulatory Approval following its receipt, safety monitoring as further described in Section 5.7 below, promotional activities, compliance, and annual reporting to such Regulatory Authorities, as well as associated document retention, and (2) filing any and all Regulatory Materials for subsequent indications in the Shared Territory, and holding any such Regulatory Materials, amendments or supplements thereto. Takeda shall be responsible for any field alert reporting and Cell Genesys shall reasonably assist Takeda with its annual reporting obligations.

**(iii)** Upon the request of the Party that is not primarily responsible for regulatory activities in the Shared Territory at a particular time, the responsible Party shall inform the applicable Regulatory Authority that one (1) or more representatives of the other Party will attend and, to the extent permitted by applicable Law, participate in all major meetings between the responsible Party and such Regulatory Authority, subject to the confidentiality provisions set forth under Article 12. The responsible Party shall timely inform the other Party of any such scheduled meetings, as soon as practicably possible.

**(iv)** Cell Genesys, in consultation with Takeda, shall be primarily responsible for the preparation of any components of Regulatory Materials to be filed by Takeda that relate to the Manufacture of Product. Takeda, in consultation with Cell Genesys, shall be primarily responsible for communicating with Regulatory Authorities in the Shared Territory regarding such Regulatory Materials filed by Takeda that relate to the Manufacture of Product. Takeda shall cooperate with Cell Genesys and take such actions as Cell Genesys may reasonably request in connection with the foregoing activities and communications as related to the Manufacture of Product for the Shared Territory.

**(v)** Takeda and Cell Genesys shall through the JDC establish a plan and schedule of regulatory activities to be performed by the Parties in connection with obtaining

approval for the first MAA for the Product in the Shared Territory and for amendments or supplements thereto.

**(b) ROW Territory.**

**(i)** Cell Genesys shall retain sponsorship of the clinical trial applications currently active in Canada [for the VITAL-1 Study and the VITAL-2 Study (CTA file no. 9427-C2383-221C)] and in Europe [for the VITAL-1 Study (EudraCT No. 2005-002738-36) and the VITAL-2 Study (EudraCT No. 2005-003275-20)] and all filings associated therewith, and Takeda shall have the right to reference such Regulatory Materials pursuant to Section 5.6 below. Cell Genesys shall not withdraw such Regulatory Materials without prior consultation with and approval of Takeda.

**(ii)** Takeda shall be the responsible party in consultation with Cell Genesys, for preparing, filing and holding any and all Regulatory Materials for the Product in the ROW Territory associated with any MAA for the Product or amendments or supplements thereto, except as provided in Section 5.2(b)(i). Such Regulatory Materials and related Regulatory Approvals shall be owned solely by Takeda and held in its name, subject to Cell Genesys' rights of reference under this Agreement.

**(iii)** Upon the request of Cell Genesys, Takeda shall inform each applicable Regulatory Authority in the ROW Territory that one (1) or more representatives of Cell Genesys will attend and, to the extent permitted by applicable Law, participate in all major meetings between Takeda and such Regulatory Authority, subject to the confidentiality provisions set forth under Article 12. Takeda shall timely inform Cell Genesys of any such scheduled meetings, as soon as practicably possible.

**(iv)** Cell Genesys, in consultation with Takeda, shall be primarily responsible for the preparation of any components of Regulatory Materials to be filed by Takeda that relate to the Manufacture of Product. Takeda, in consultation with Cell Genesys, shall be primarily responsible for communicating with Regulatory Authorities in the ROW Territory regarding such Regulatory Materials filed by Takeda that relate to the Manufacture of Product. Takeda shall cooperate with Cell Genesys and take such actions as Cell Genesys may reasonably request in connection with the foregoing activities and communications as related to the Manufacture of Product for the ROW Territory.

**(v)** Each Party shall assist the other Party as reasonably requested in connection with the preparation and filing of Regulatory Materials for the ROW Territory. The Parties agree and acknowledge that the regulatory strategy for the ROW Territory shall be coordinated with Parties' activities in the Shared Territory and consistent with the overall objective of facilitating Regulatory Approval in both the ROW Territory and Shared Territory.

**5.3 Cooperation, Consultation and Review.** The Parties shall establish a joint regulatory working group and shall cooperate with each other to achieve the regulatory objectives contemplated herein in a timely, accurate and responsive manner. Each Party shall assist the other Party as such other Party may reasonably request in connection with the preparation and filing of all Regulatory Materials contemplated in this Article 5. Each Party

shall provide the other Party with copies of any proposed Regulatory Materials to be submitted by such Party (other than routine correspondence) and shall reasonably consider any comments thereto provided by the other Party to the extent practicable.

**5.4 Regulatory Costs and Expenses.** Any costs and expenses incurred by either Party related to the preparation, maintenance, formatting and filing of the Regulatory Materials in the Field in the Licensed Territory shall be borne solely by Takeda; provided, however, that Cell Genesys will bear its Internal FTE Costs associated with regulatory activities conducted by it in support of the first MAA approval for the Product for the Shared Territory and will bear all costs and expenses associated with regulatory activities in support of Regulatory Materials for which Cell Genesys is responsible as expressly provided above and in Section 4.3(b)(i). Any reimbursement due Cell Genesys pursuant to this Section 5.4 will be made pursuant to the procedures described in Section 4.3(c).

**5.5 [Intentionally left blank.]**

**5.6 Rights of Reference to Regulatory Materials**. Each Party hereby grants to the other Party a right of reference to all Regulatory Materials filed by such Party for the Product solely for the purpose of seeking, obtaining and maintaining Regulatory Approvals for, and the Commercialization of, the Products in the Licensed Territory, consistent with the roles of the Parties set forth in this Agreement. In addition, Takeda hereby grants to Cell Genesys a right of reference free of charge, to all Regulatory Materials related to the VITAL Studies, Currently Ongoing Studies, Product mechanism of action and Product safety information generated pursuant to the Development here under filed by Takeda in the Licensed Territory solely for the purpose of Cell Genesys, its Affiliates or any Third Party licensees to develop and obtain and/or maintain regulatory approvals anywhere in the world for GVAX products outside the Field. Cell Genesys shall have the right to reference (and to grant Third Parties the right to reference) any other Regulatory Materials filed by Takeda in the Licensed Territory generated by or on behalf of Takeda or its Affiliates with respect to Additional Studies conducted here under (the **"Other Regulatory Materials"**), [subject to the payment of a royalty for such Other Collaboration Data under Section 8.10] and subject to the rights granted to Takeda under this Agreement for the Product in the Field, solely for the purpose of Cell Genesys, its Affiliates or any Third Party licensees to develop and obtain and/or maintain regulatory approvals anywhere in the world for GVAX products outside the Field. Cell Genesys shall notify Takeda promptly of all such uses.

**5.7 Adverse Event Reporting and Safety Data Exchange.**

**(a) Prior to First MAA Approval.** The Parties agree that Cell Genesys will be primarily responsible for the monitoring of all clinical experiences, maintaining the global safety database, safety monitoring, pharmacovigilance surveillance, compliance and filing of all required safety reports to Regulatory Authorities in the Licensed Territory, including without limitation annual safety reports, throughout the Development of the Product up to the first MAA approval in the Licensed Territory (or such earlier date as the Parties may agree in writing is reasonably appropriate to transition such responsibility given regulatory considerations and the best interest of the Product) and thereafter as and to the extent required by applicable Law for any study conducted under an IND held by Cell Genesys. Takeda shall have the right to review all such information at reasonable times, upon written request.

**(b) Following First MAA Approval.** Promptly following the first MAA approval in Licensed Territory (or such earlier date as the Parties may agree in writing is reasonably appropriate to transition such responsibility given regulatory considerations and the best interest of the Product), Takeda will assume all responsibility for the activities described in Section 5.7(a) (except for activities for filings held in the name of Cell Genesys), including but not limited to maintaining the global safety database for the Product and being primarily responsible for pharmacovigilance. The Parties shall cooperate to develop methods and/or procedures for transitioning the activities described in this section to Takeda. Cell Genesys shall have the right to review all such information at reasonable times, upon written request.

**(c) Safety Information Exchange; Agreement.** The Parties shall cooperate to develop methods and/or procedures for sharing information relating to the clinical experiences referred to in Sections 5.7(a) and (b) in accordance with safety reporting requirements of the respective Regulatory Authorities and as necessary for a Party to comply with applicable Law. Specific details regarding the management of safety information including adverse events reports related to the clinical development and the commercial use of the Product in the Licensed Territory will be delineated in a separate safety information exchange agreement that shall be agreed to by the Parties as soon as practicable after the Effective Date but not later than two (2) weeks prior to the earlier of (i) the anticipated date of first transfer of the IND from Cell Genesys to Takeda in the Licensed Territory, (ii) IND submission in Japan, or (iii) the initiation of any Additional Studies conducted before the first Regulatory Approval. Following submission of the first MAA until such time as the global safety data base is transferred to Takeda, Cell Genesys shall prepare and provide to Takeda on a timely basis safety updates in order for Takeda to meet the safety report submission requirements of the applicable Regulatory Agencies in the Licensed Territories, as more particularly described in the aforementioned safety information exchange agreement.

**(d) Regulatory Reporting.** Each Party shall be permitted, and have the right, to perform pharmacovigilance activities and/or make such safety reports to applicable Regulatory Authorities, to comply with applicable Laws, international best practices for pharmacovigilance activities and/or other activities that the Party, in its reasonable and good faith judgment, believes necessary for the health, safety and protection of patients and/or clinical trial subjects. The Parties shall work together to agree to one opinion with respect to safety issues and to report said opinion to safety boards of any nature, investigators, and to applicable Regulatory Authorities. In the event that, after reasonable medical and scientific consultation, the Parties cannot agree to one opinion with respect to safety issues to be reported to any applicable Regulatory Authority, including but not limited to, individual adverse events or other matters affecting the health, safety or welfare of a patient, then, notwithstanding the provisions of Article 3, the Parties shall follow the dispute resolution procedure provided in Section 14.3(b). For clarity, the obligation to follow such dispute resolution procedure shall not limit either Party's right, as provided in the first sentence of this Section 5.7(d), to report safety matters to Regulatory Authorities that may be necessary prior to the conclusion of the dispute resolution procedure.

**5.8 Regulatory Authority Communications Received by a Party.** Each Party shall keep the other Party informed in a timely manner compliant with the reporting requirements of Regulatory Authorities in the Licensed Territory of notification of any action by, or notification or other information which it receives (directly or indirectly) from any Regulatory Authority

which: (i) raises any material concerns regarding the safety or efficacy of the Product; (ii) indicates or suggests a potential material liability of either Party to Third Parties in connection with the Product; (iii) is reasonably likely to lead to a recall or market withdrawal of the Product; or (iv) relates to expedited and periodic reports of adverse events with respect to the Product, or Product Complaints, and which may have a material impact on Regulatory Approval or the continued Commercialization of the Product. The other Party will fully cooperate with and assist such Party in complying with regulatory obligations and communications, including by providing to such Party, in a timely manner after a request, such information and documentation in the other Party's possession as may be necessary or helpful for the Party to prepare a response to an inquiry from a Regulatory Authority. Each Party will provide the other Party in a timely manner with a copy of all correspondence received from a Regulatory Authority specifically regarding the matters referred to above.

**5.9 Audit**. If a Regulatory Authority desires to conduct an inspection or audit of a Party's facility or a facility under contract with such Party with regard to the Product in the Licensed Territory, then the audited Party shall notify the other Party as soon as practicably possible after receipt of such notification of such audit or inspection and provide copies of any materials provided to it by the applicable Regulatory Authority; provided, that the audited Party shall not be required to notify the other Party of audits or inspections that are of a routine nature or that do not relate to the Product or the Field, except where such audits result in communications or actions of such Regulatory Authority which have an impact upon the Product. In addition, if a Regulatory Authority conducts an unannounced inspection or audit of a Party's facility or a facility under contract with such Party with regard to the Product in the Licensed Territory, then the audited Party shall notify the other Party within twenty-four (24) of commencement of such audit or inspection. The audited Party shall cooperate, and shall use reasonable efforts to cause the contract facility to cooperate, with such Regulatory Authority and the other Party during such inspection or audit. Following receipt of the inspection or audit observations of such Regulatory Authority (a copy of which the audited Party will immediately provide to the other Party), the audited Party will also provide the other Party with copies of any written communications received from Regulatory Authorities with respect to such facilities in a timely manner after receipt, to the extent such written communications relate to the Product or the Manufacture thereof, and will prepare the response to any such observations. The audited Party will provide the other Party with a copy of any proposed response to such communications and will implement such other Party's reasonable comments with respect to such proposed response. The audited Party agrees to conform its activities under this Agreement to any commitments made in such a response.

## ARTICLE 6

## COMMERCIALIZATION

**6.1 Overview of Commercialization in the Licensed Territory**. Subject to the Co-Promotion Option described in Section 6.12 and the other terms and conditions of this Article 6, as between the Parties, Takeda will be responsible for all aspects of the Commercialization of the Product in the Field in the Licensed Territory, including, without limitation: (a) developing and executing a commercial launch and pre-launch plan, (b) marketing and promotion; (c) booking sales and distribution and performance of related services; (d) handling all aspects of order

processing, invoicing and collection, inventory and receivables; (e) publications, (f) providing customer support, including handling medical queries, and performing other related functions; and (g) conforming its practices and procedures in all material respects to the applicable Laws relating to the marketing, detailing and promotion of the Products in the Field in the countries of the Licensed Territory. Except as otherwise provided in this Article 6, Takeda shall bear all of the costs and expenses incurred in connection with all such Commercialization activities.

**6.2 Commercialization Plan for Shared Territory**. Takeda shall Commercialize the Products in the Shared Territory pursuant to a detailed plan prepared by Takeda and submitted to the JCC for review, comment and, if the Co-Promotion Option is exercised, approval (the "**Commercialization Plan**"). The Commercialization Plan will include information, budgets and timelines regarding Takeda's Commercialization activities, including Product life cycle management, pricing, reimbursement, market research, sales training, distribution channels, customer service and sales force matters related to the launch and sale of the Product in the Field and in the Shared Territory. The initial Commercialization Plan shall be delivered to the JCC not later than [March 31, 2009]. On at least an annual basis (no later than December 1 of each calendar year, commencing in [2009]), Takeda shall update and amend, as appropriate, the then-current Commercialization Plan. Takeda shall submit all updates and amendments to the Commercialization Plan to the JCC for review and comment, and, if Cell Genesys exercises the Co-Promotion Option, approval. The Parties agree that Takeda will have planning, oversight, and final decision making authority (as provided expressly in Section 14.2) and responsibility for all sales, marketing, and promotional activities related to the Product as expressly described in this Agreement. Cell Genesys will have the opportunity, through the JCC, to confer with Takeda on such sales, marketing and promotional matters. For the avoidance of doubt, Takeda shall have the sole right to determine the physician target list, as well as the optimal frequency to each physician target (together the "Detail Plan") as part of the Commercialization Plan.

**6.3 Product Distribution**.

**(a)** Takeda shall have responsibility for Distribution of the Product in the Shared Territory. Cell Genesys shall confer with Takeda on the design of the commercial distribution channels for the Shared Territory in order to share such distribution research and planning already developed by Cell Genesys. The Joint Commercial Committee shall review and approve the design of the commercial distribution channels for the Shared Territory, to be described in the then-current Commercialization Plan. Not later than [December 31, 2008], the JCC may request Cell Genesys to assume responsibility for some or all of the Distribution activities and Cell Genesys, subject to its agreement, shall undertake such Distribution activities in accordance with the Commercialization Plan. Takeda shall reimburse Cell Genesys for any expenses incurred by Cell Genesys in connection with such distribution in accordance with terms and conditions to be set forth in the Supply Agreement.

**(b)** The Parties agree that Takeda, in consultation with the JCC, will have planning, oversight, and decision making authority and responsibility for all Distribution of Product in the ROW Territory.

**6.4 Pricing; Reimbursement**.

**(a)** Takeda shall have the sole right to determine all pricing of the Product in the Licensed Territory. Notwithstanding anything in this Agreement express or implied to the contrary, Cell Genesys shall not have any right to direct, control, or approve Takeda's pricing of Products for the Licensed Territory. The provision to Cell Genesys of any pricing data in connection with the Commercialization Plan is for informational purposes only.

**(b)** Takeda shall have the sole right to determine the reimbursement strategy for the Product. Cell Genesys shall confer with Takeda on the development of the reimbursement strategy for the Product for the initial indication in the Shared Territory in order to share the research and planning information relating to reimbursement processes already developed by Cell Genesys. The JCC shall review the reimbursement strategy to be described in the then-current Commercialization Plan for such indication, which may provide, subject to JCC approval, for Cell Genesys to continue developing processes related to reimbursement.

**6.5 Commercial Diligence**. Takeda shall devote Diligent Efforts to Commercialize each Product throughout the Licensed Territory following receipt of Regulatory Approval of such Product in accordance with this Agreement. Without limiting the foregoing, Takeda shall achieve First Commercial Sale of the Product in the Shared Territory within [six (6)] months after receipt of Regulatory Approval of the Product in such territory; provided that failure to achieve such First Commercial Sale within such time shall not be a breach of this Agreement to the extent directly attributable to the action or inaction of Cell Genesys.

**6.6 Reports**. In addition to Takeda's obligations under Section 6.2, each Party shall update the JCC, and JDC as applicable to lifecycle management of the Product, at each meeting regarding its significant Commercialization activities with Products in the Licensed Territory. Each such update shall be in a form to be agreed by the JCC and shall summarize such Party's significant Commercialization activities with respect to Products in the Licensed Territory pursuant to this Agreement, include a forecast for the following year's sales of the Product in the Licensed Territory, and describe success rates for the distribution and sales channels for the Product.

**6.7 Coordination of Marketing Activities**. Subject to Section 14.2(b)(ii), the JCC shall be responsible for coordinating any marketing activities by Takeda for Commercialization of the Product in the Field and in the ROW Territory, with the activities of the Parties in the Shared Territory, including without limitation, the education of medical practitioners and caregivers.

**6.8 Compliance**.

**(a) Shared Territory.** Takeda, its Affiliates and sublicensees and Cell Genesys, in Commercializing the Products (including performing Details), shall comply with all applicable Laws applicable to the marketing, sale and promotion of pharmaceutical products, including, without limitation, the statutes, regulations and written directives of the FDA, including the FD&C Act, the Prescription Drug Marketing Act, the Federal Health Care Programs Anti-Kickback Law, 42 U.S.C. 1320a-7b(b), the statutes, regulations and written directives of Medicare, Medicaid and all other health care programs, as defined in 42 U.S.C. § 1320a-7b(f) the Health Insurance Portability and Accountability Act of 1996, the Pharmaceutical Research and

Manufacturers of America Code on Interactions with Healthcare Professionals, and the American Medical Association Guidelines on Gifts to Physicians from Industry, each as may be amended from time to time. Consistent with the "Compliance Program Guidance for Pharmaceutical Manufacturers," published by the Office of Inspector General, U.S. Department of Health and Human Services (the "OIG Guidance"), each Party agrees to maintain a compliance program with respect to its promotional and sales activities pursuant to this Agreement containing all of the elements described in such guidance document. The Parties shall provide each other with copies of their policies for such compliance programs.

**(b) ROW Territory**. Takeda, its Affiliates and sublicencees shall comply with all applicable Laws and guidelines in the ROW Territory applicable to the marketing, sale and promotion of pharmaceutical products.

**(c) No Obligation.** No Party shall be required to take any action, undertake any obligation, or incur any cost or reimbursement obligation, in connection with any activity under this Agreement that such Party believes, in good faith, may violate any applicable Laws or the aforementioned code, guidelines and OIG Guidance.

**(d) Pre-Launch Activities.** Prior to the receipt of the first Regulatory Approval for the Product by each of the FDA, Health Canada or the EMEA for the applicable territory, Cell Genesys, through the JCC, shall have the right to review, comment on and approve (not to be unreasonably withheld, conditioned or delayed) any proposed Commercialization activities of Takeda intended to occur in the applicable Territory prior to such Regulatory Approval by the applicable Regulatory Authority, including without limitation any materials proposed to be used by Takeda in such Commercialization activities. The JCC shall determine a process that assures the expedient and efficient review of such materials by Cell Genesys so as not to disrupt or delay such Commercialization activities.

### 6.9 Trademark Matters.

**(a) Product Mark.** It is the intention of the Parties that the Product be sold and marketed [under a single worldwide brand, where practicable and commercially viable]. Notwithstanding the foregoing, the Parties acknowledge such [a single brand] approach is not viable [for the Japanese market] and may not be viable for [other countries of the ROW Territory]. Takeda shall propose such trademark or trademarks for the Product, which shall be approved by the JCC (the "**Product Mark**"), and which may include an existing Product trademark owned by Cell Genesys (which such trademarks are set forth on Exhibit G). Following selection of the Product Mark, the Parties will grant such royalty-free licenses as may be necessary to facilitate the worldwide marketing of the Product using such mark or marks. For the avoidance of doubt, the Parties are not obligated to use any of the trademarks set forth on Exhibit G as the Product Mark but the foregoing does not limit Takeda's obligations with respect to any CG Marks described in Section 6.9(b). The Product Mark, if a mark other than any of the trademarks set forth on Exhibit G, shall be owned by Takeda.

**(b) CG Marks.** The Parties anticipate using certain of Cell Genesys' existing "GVAX" marks to describe the immunotherapy technology upon which the Product is based and Cell Genesys' house marks to identify Cell Genesys as the source of such technology and as the

manufacturer of Product (collectively, the "**CG Marks**"). Provided such uses comply with applicable Laws and market practice in the various countries of the Licensed Territory, (i) the Cell Genesys house mark shall be used on the Product label, packaging and promotional/marketing material, and shall be displayed with equal prominence as the Takeda house mark, and (ii) the GVAX marks shall be used, where feasible and appropriate, in connection with any Product promotional material that refers to Cell Genesys' immunotherapy technology. The CG Marks existing as of the Effective Date are set forth on Exhibit G. Cell Genesys hereby grants to Takeda a royalty-free, non-exclusive license to use such CG Marks solely in connection with the Commercialization of the Product in the Field in the Licensed Territory. Takeda shall provide Cell Genesys with samples of any advertising and promotional materials that incorporate the CG Marks prior to distributing such materials for use. Takeda acknowledges Cell Genesys' exclusive ownership of the CG Marks and agrees not to take any action inconsistent with such ownership. Takeda shall not use any CG Mark in a way that would adversely affect its value. Takeda covenants that it shall not use any trademark confusingly similar to any CG Mark in connection with any products (including the Product). Takeda shall comply with reasonable policies provided by Cell Genesys from time to time to maintain the goodwill and value of the CG Marks.

**(c) Takeda Marks**. Cell Genesys shall provide Takeda with samples of any materials that incorporate the Takeda Marks prior to distributing such materials for use. Cell Genesys acknowledges Takeda's exclusive ownership of the Takeda Marks and agrees not to take any action inconsistent with such ownership. Cell Genesys shall not use any Takeda Mark in a way that would adversely affect its value. Cell Genesys covenants that it shall not use any trademark confusingly similar to any Takeda Mark in connection with any products (including the Product). Cell Genesys shall comply with reasonable policies provided by Takeda from time to time to maintain the goodwill and value of the Takeda Marks.

**6.10 Additional Marketing Activities.** Cell Genesys shall have the right to provide additional marketing (as distinct from Detailing or promotional) support for the Product in the Shared Territory, at its own cost, in a manner to be described in the Commercialization Plan, including by maintaining its existing relationships with key opinion leaders and developing additional contacts, and by sponsoring or participating in medical education activities, including conference and exhibit booths. All such activities of Cell Genesys related to the Product will be consistent with messaging and strategy provided by Takeda and coordinated by the JCC.

**6.11 Publication**

**(a) Strategy**. The Publication Team, established pursuant to Section 6.11(b), in close cooperation with the JDC and JCC will agree in advance on any publication of study results from the VITAL Studies, Currently Ongoing Studies, or Additional Studies and prepare a joint publication strategy and publication plan, subject to the provisions of this Section 6.11.

**(b) Publication Team**. The JSC shall establish a Publication Team composed of an equal number of representatives from each of Takeda and Cell Genesys with the reasonable balance of medical and scientific qualifications to agree on the detailed planning of the publication strategy and publication plan detailing the intended timing, venue, media, authors etc. for all publications of matters covered under this Section 6.11 including scientific articles, abstracts and posters intended for presentation at congresses. All health economic publications and

communication at any congress shall be an integrated part of the publication strategy and plan. The Publication Team shall be co-chaired by representatives from both Parties and shall convene as deemed necessary to accomplish the above. In case of any dispute concerning publication the matter shall be referred to the JSC for resolution; provided, however, any such resolution shall be consistent with the guidelines set forth in Section 6.11(d).

**(c) Publication Review**. Except for disclosures permitted pursuant to Section 12.1 and consistent with the mutually agreed publication strategy pursuant to Section 6.11(a), either Party, its employees or consultants wishing to make a publication in the Licensed Territory of matters covered under this Section 6.11 shall deliver to the other Party a copy of the proposed written publication or an outline of an oral disclosure at least sixty (60) days (or earlier if reasonably practicable, or within forty-five (45) days with respect to agreements existing as of the Effective Date that Cell Genesys has with a Third Party performing clinical trials, research or the like in connection with such publication) prior to submission for publication or presentation. The reviewing Party shall have the right (a) to propose modifications to the publication or presentation for patent reasons or trade secret reasons and/or (b) to request a reasonable delay in publication or presentation in order to protect patentable information. If the reviewing Party requests a delay, the Parties shall in good faith discuss and agree on the timing of such publication and if the Parties cannot agree the publishing Party shall delay submission or presentation for a period of sixty (60) days (or forty-five (45) days with respect to agreements existing as of the Effective Date that Cell Genesys has with a Third Party performing clinical trials, research or the like in connection with such publication) to enable patent applications protecting each Party's rights in such information to be filed in accordance with Article 9 below. Upon expiration of such sixty (60) days (or forty-five (45) days as provided above), the publishing Party shall be free to proceed with the publication or presentation. If the reviewing Party requests modifications to the publication or presentation, the publishing Party shall edit such publication to prevent disclosure of trade secret or proprietary business information prior to submission of the publication or presentation.

**(d) Standards.** All publications of matters covered under this Section 6.11 shall be prepared, presented and/or published in accordance with pharmaceutical industry accepted guidelines including, but not limited to: (1) International Committee of Medical Journal Editors (ICMJE) guidelines, (2) Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication, (3) Pharmaceutical Research and Manufacturers of America (PhRMA) guidelines, and (4) PhRMA Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results.

### 6.12 Co-Promotion Option.

**(a) Exercise Periods.** Cell Genesys will have the option, upon written notice, to elect to promote and Detail the Product in the Shared Territory jointly with Takeda, as described in this Section 6.12 (the "**Co-Promotion Option**"). Cell Genesys will have two opportunities to exercise the Co-Promotion Option, unless otherwise agreed by the Parties. The first such opportunity shall commence on the Effective Date and end [eighteen (18) months] prior to the anticipated launch date as set forth in the then-current Commercialization Plan (the "**Pre-Launch Window**"); the second such opportunity shall commence on the date [twenty four (24) months] after the First Commercial Sale of the Product in the Shared Territory and continue for the remainder of the Term (the "**Post-Launch Window**"). Cell Genesys may exercise such Co-

Promotion Option by delivering written notice thereof to Takeda during either the Pre-Launch Window or the Post-Launch Window. Upon such exercise, Cell Genesys' right to co-promote shall commence as soon as practicable thereafter, as agreed by the Parties, but in no event earlier than [twelve (12)] months following the date of such exercise, if such exercise was made during the Post-Launch Window. During the foregoing [twelve (12)] month period, the Parties agree that Cell Genesys may conduct planning and other pre-commercial activities as it determines are reasonably appropriate for Cell Genesys to promptly commence Detailing on the date that is [twelve (12)] months following the date of such exercise.

**(b) Detailing Effort.** If Cell Genesys exercises the Co-Promotion Option during the Pre-Launch Window, then Cell Genesys will have the right to contribute up to fifty percent (50%) of the total Details for the Product to oncologists in the Shared Territory as required under the Commercialization Plan. If Cell Genesys exercises the Co-Promotion Option during the Post-Launch Window, then Cell Genesys will have the right to contribute up to thirty percent (30%) of the total Details for the Product to oncologists in the Shared Territory as required under the Commercialization Plan.

**(c) Terms of Co-Promotion.** In either case of exercise of the Co-Promotion Option, the following will apply:

**(i)** the Parties shall negotiate and enter into a separate co-promotion agreement promptly following Cell Genesys' exercise of the Co-Promotion Option containing the terms set forth in this Section 6.12 as well as the terms and conditions set forth in Exhibit D, and such other reasonable and customary terms as the Parties may agree (the "**Co-Promotion Agreement**");

**(ii)** Subject to the approval of the JCC, Cell Genesys may contribute to strategic marketing efforts with respect to the Product in the Shared Territory, (1) at Cell Genesys' cost, if Cell Genesys requests to conduct such efforts, and/or (2) at Takeda's cost if Takeda requests that Cell Genesys conduct such efforts;

**(iii)** Details to be conducted by Cell Genesys' sales force will be provided in accordance with the Commercialization Plan and the Co-Promotion Agreement; and

**(iv)** Takeda will compensate Cell Genesys for co-promoting the Product through payments based on number and type of Details provided by Cell Genesys' sales force, with the per-Detail payments to be based on independent third party comparable payments for similar prescriber specialties and a sales force having expertise sufficient to promote the Product.

## ARTICLE 7

## MANUFACTURE AND SUPPLY

**7.1 General Supply Terms.** Cell Genesys shall (i) itself or through one or more Third Party contract manufacturers, Manufacture the Product (as defined in Section 1.69(a)) in accordance with the terms of Sections 7.2, 7.3 and 7.4, including the performance of all manufacturing process development, scale-up, and validation for such Product (and associated

regulatory activities), inventory build-up and retention, (ii) be the primary source of Product (as defined in Section 1.69(a)) required by the Parties in the Licensed Territory for Non-Clinical Studies, clinical and Commercialization activities as and to the extent set forth in this Agreement, and (iii) supply Takeda's requirements of Product as determined in accordance with the provisions of this Article 7, Exhibit E and the Supply Agreement. Cell Genesys shall have the right to Manufacture and supply to Takeda all of its requirements for Additional Products in accordance with the terms of this Agreement. Upon such election or the request of Takeda, Cell Genesys shall supply quantities of Additional Product required for Development as determined in accordance with the provisions of this Article 7, Exhibit E and the Supply Agreement. If Cell Genesys does not elect to supply Additional Product for Commercialization, Cell Genesys, at the request of Takeda, shall supply quantities of Additional Product required for Commercialization in the event that Takeda is unable to secure a source (including Takeda itself) of supply (other than Cell Genesys) for such Additional Product, following Takeda's exercise of Diligent Efforts to secure such source. The terms and conditions applicable to the Manufacture and supply of such Additional Product shall be as described in this Article 7 for the Product (as defined in Section 1.69(a)), Exhibit E and the Supply Agreement, to the extent commercially and technically feasible. If such terms and conditions are not commercially and technically feasible with respect to Additional Product, then the Parties will use reasonable and good faith efforts to determine such terms and conditions upon the designation of an Additional Product under this Agreement; provided, in any event the price of such Additional Product shall be Cell Genesys' Clinical Supply Cost or Fully Burdened Manufacturing Cost, as applicable to Product under this Article 7 or Exhibit E. Takeda shall purchase (or for clinical supplies reimburse) all of its, its Affiliates and sublicensees' requirements for Products as and to the extent set forth in this Agreement.

**7.2 Clinical Supply**. Cell Genesys will provide all quantities of Product for use in the Development of such Product prior to receipt of the first Regulatory Approval for the Product in the Licensed Territory, in accordance with the terms and conditions in this Section 7.2 below or, after executed, the terms and conditions in the Supply Agreement. Unless expressly provided otherwise in this Article 7 or Exhibit E, the terms contained in this Section 7.2 are intended to apply only to the supply of Product for Development activities prior to the first Regulatory Approval.

**(a) Forecasting**. In consultation with Takeda, Cell Genesys will be responsible for forecasting all quantities of Product to be used in connection with the VITAL Studies, Currently Ongoing Studies and any Additional Studies performed or monitored by Cell Genesys. Takeda, through the JDC, will furnish to Cell Genesys a rolling [eighteen (18) month] forecast of estimated monthly requirements for clinical quantities of Product for any Additional Studies performed or monitored by Takeda, to be updated every [three (3) months] (or such other time as the Parties may agree) based upon Takeda's good faith estimate of its needs for Product, and to include a binding forecast for the [ninety (90) day] period immediately following the date of such forecast.

**(b) Supply of Product**. Cell Genesys will provide all quantities of Product necessary to conduct the VITAL Studies, the Currently Ongoing Studies and any Additional Studies as may be required to perform such studies as and to the extent set forth in the Shared Territory Development Plan or the ROW Development Plan. Cell Genesys will deliver such

Product in accordance with current Distribution procedures until such time as Takeda has established and qualified Distribution capability and assumed responsibility for Distribution; thereafter, Cell Genesys will deliver such Product in accordance with the timeframes established by the parties through the JDC necessary to support the VITAL Studies, the Currently Ongoing Studies and any Additional Studies. Cell Genesys will use Diligent Efforts to deliver each order on or before the applicable delivery date.

**(c) Reimbursement**. Cell Genesys will include its Clinical Supply Costs as Reimbursable Expenses pursuant to the terms of Article 4 above.

**(d) Delivery**. Unless otherwise agreed by the parties in writing, Cell Genesys will ship (and bear the risk of loss during transportation for) Product to the destinations designated for each applicable Development activity. Cell Genesys will package and ship Product in accordance with the then-current Specifications and Cell Genesys' customary practices for Products.

**(e) Limited Warranty**. Cell Genesys warrants that Product delivered hereunder will at the time of delivery: (i) be manufactured and tested in accordance with the applicable IND, U.S. Good Manufacturing Practices and all other Laws applicable to the use of such Product for Development, (ii) conform to the Specifications, and (iii) not be adulterated or misbranded within the meaning of FD&C Act, 21 U.S.C. §301c et. seq. Any lot of Product delivered by Cell Genesys which does not conform to the warranty provided in this Section 7.2(e) and is found to be non-conforming within ninety (90) days of delivery will be replaced by Cell Genesys at no further charge, or, at Takeda's option, the cost thereof shall be repaid to Takeda. The foregoing remedy constitutes Takeda's sole and exclusive remedy with respect to any quantity of Product that fails to conform to Specifications.

**(f) Audit Right**. Cell Genesys shall permit, and shall cause any of its contract manufacturers to permit, Takeda, its Affiliates and/or representatives to audit any facilities at which the Product and/or components of the Product are manufactured, stored or tested for the purpose of determining compliance with the Specifications, Good Manufacturing Practices and any applicable Laws during regular business hours following reasonable notice. Such audits may be conducted no more than once per calendar year; provided, however, if any notice or observation is made by a Regulatory Authority of noncompliance of such facility with applicable Law in connection with Product or any components of Product, Takeda may conduct an audit of such facility more frequently than as provided above to the extent necessary to confirm that the relevant matters in such notice or observation are adequately addressed. Cell Genesys shall reasonably cooperate with Takeda to facilitate such audit, including but not limited to providing prompt follow up reports to Takeda describing the resolution to any audit findings or observations noted by Takeda during or following its audit of such facilities. Takeda's exercise of these audit rights shall in no way waive, modify or diminish Cell Genesys' supply obligations under this Agreement or the Supply Agreement.

**7.3 Supply Agreement**. On or before a date to be established by the JSC but in no event later than [December 31, 2008], the Parties shall enter into (i) a supply agreement governing the supply of Product to Takeda for Development following receipt of the first Regulatory Approval and for commercial use (the "**Supply Agreement**") and (ii) a quality

agreement governing the quality control, quality assurance and validation of such Product (the "**Quality Agreement**"). The terms of such Supply Agreement and such Quality Agreement shall be negotiated in good faith by the Parties and, with respect to the Supply Agreement, will contain the terms described in Article 7, Exhibit E and such other terms and conditions reasonable and customary for agreements of such type, as agreed by the Parties.

**7.4 Supply Security.**

**(a) Second Source Plan**. On or before a date to be established by the JSC but in no event later than [December 31, 2008] and in connection with the Supply Agreement, the JSC shall approve a plan developed by the Parties for sourcing Product from Takeda or other potential manufacturing sites in addition to Cell Genesys' Hayward facility. The detailed terms of such second source rights will be set forth in a second source plan (the "**Second Source Plan**") to be included as part of the Supply Agreement, as and to the extent agreed by the Parties in accordance with the terms of this Agreement. The Parties agree and acknowledge that the Second Source Plan will be developed with the objectives of maximizing the utilization of Cell Genesys' capacity where possible and ensuring a continuity of supply in the event of a supply failure by Cell Genesys. The Parties will cooperate regarding the establishment and implementation of such Second Source Plan, to include the screening and selection of potential Product manufacturers, negotiating the applicable supply agreements, ensuring the capability and qualification of manufacturers and necessary technology transfer. Takeda shall pay all costs associated with the second source supply for the Product (including internal and out of pocket expenses), including establishing, qualifying, initiating and maintaining such second source supplier as to be set forth in the Second Source Plan.

**(b) Implementation of the Second Source Plan; Technical Transfer of Manufacturing Method**. The Parties agree that the Second Source Plan shall provide for initiation of activities relating to the implementation of the Second Source Plan. In addition, upon Takeda's request, Cell Genesys shall transfer the Information regarding the Manufacturing process and methods to Takeda, its Affiliates and/or Third Parties; provided, however, such request shall not be made before [December 31, 2008] or during the [three (3) month] period prior to the anticipated date of first commercial launch in the Shared Territory and further provided that the timing and nature of such request shall not adversely affect Cell Genesys' ability to Manufacture the Product. Notwithstanding the foregoing, [Takeda shall be permitted to make such request with sixty (60) days prior notice during such prohibited periods if Takeda determines in good faith that there is a material risk that Cell Genesys will not be able to meet the then-current forecast of Product demand for either Development or commercial use.] Cell Genesys shall provide reasonable support for such transfer (including without limitation preparation of regulatory documents) along with key raw materials such as cell strains and other proprietary knowledge necessary for manufacture of Product. The costs for such transfer and services shall be borne by Cell Genesys.

**(c) Safety Stock**. On or prior to the expected date of First Commercial Sale of the Product, Cell Genesys shall Manufacture and maintain at a designated facility a safety supply of Product inventory equal to a [six (6) month] supply based upon Takeda's then-current forecast (and at least the first [three (3) months] of such forecast shall be binding) for the Product during such period following First Commercial Sale of the Product (or such other amount as

agreed by the Parties taking into consideration commercial factors and Regulatory Authority determination regarding packaging and labeling). Within the twelve (12) month period following First Commercial Sale of the Product, Cell Genesys shall Manufacture and maintain at a designated facility a safety supply of Product inventory in a quantity to be reasonably agreed in good faith by the Parties taking into consideration Takeda's binding forecast for the Product, aggregate cycle lead time from initiation of Manufacture of a Product batch to delivery and applicable industry standard practices. [Cell Genesys shall be responsible for the cost of Manufacturing and maintaining such safety stock.] The detailed terms regarding the availability and use of such safety stock shall be described in the Supply Agreement.

**7.5 Recalls and Voluntary Withdrawals**. The Parties shall exchange their internal standard operating procedures ("**SOPs**") for conducting product recalls reasonably in advance of the First Commercial Sale of any released Product in the Shared Territory, and shall discuss and resolve any conflicts between such SOPs and issues relating thereto promptly after such exchange. If either Party becomes aware of information relating to any released Product that indicates that a unit or batch of Product may not conform to the specifications therefor, or that potential adulteration, misbranding, and/or other issues have arisen that relate to the safety or efficacy of such released Products, it shall promptly so notify the other Party. The Party having the right to control such recall pursuant to this Section 7.5 may, at its sole discretion, take appropriate courses of action, which shall be consistent with the internal SOP of such Party; provided however that such controlling Party shall promptly notify the other Party of any recall action being considered, and where practicable, consider the views of the non-controlling Party prior to taking any recall action. Takeda shall have the right to control any Product recall, field correction, or withdrawal of any released Product in the Licensed Territory. Takeda shall maintain complete and accurate records of any recall according to its then current SOPs in the Licensed Territory for such periods as may be required by applicable Laws, but in no event for less than three (3) years. The costs of any Product recall, field correction and/or withdrawal shall be borne by the applicable Party as set forth in Exhibit E.

## ARTICLE 8

## COMPENSATION

**8.1 Upfront Fee**. Within five (5) business days after the Effective Date, and in partial consideration for the prior cost of developing the Product and Takeda's rights in and to the Cell Genesys Technology licensed hereunder, Takeda shall pay to Cell Genesys a one-time upfront fee of $50,000,000. Such fee shall be nonrefundable and noncreditable against any other payments due hereunder.

**8.2 Manufacturing Milestone Payments in the Shared Territory**. Takeda shall make the following one-time, nonrefundable, noncreditable milestone payments to Cell Genesys to reimburse Cell Genesys for activities relating to Manufacture of the Product. Takeda shall pay to Cell Genesys the amount of such payment within thirty (30) days after receipt by Takeda of Cell Genesys' invoice following the achievement of each of the following performance events.

| Milestone Event | Milestone Payment |
|---|---|
| [Upon completion on or before June 30, 2009 of the third batch of each cell line (to support the comparability approach as generally agreed in a meeting with the FDA on October 26, 2007 and described in BB-IND 9678 serial 217 (Sept. 20, 2007) and serial 235 (Dec. 21, 2007)) that has been manufactured in a 500 liter bioreactor at Cell Genesys' Hayward GMP facility, with a certificate of analysis and final QA release conforming to the Specifications for the Product and with the third batch manufactured in accordance with cGMP for the Shared Territory. If such third batch is not completed by June 30, 2009, then the milestone payment will be nonetheless owed, but reduced by 50% for each 90-day period that elapses between such date and the date of completion. Such milestone will be payable upon receipt of the certificates of analysis for these six batches as described above indicating that each batch conforms to the Specifications for the Product as one of the conditions of comparability as agreed in the aforementioned October 26, 2007 meeting with the FDA. In addition, at the same time, Cell Genesys shall provide the JDC with a progress report on its commercial manufacturing scale up activities.] | [$15,000,000] |

| | |
|---|---|
| [Upon the first shipment of Product by Cell Genesys after receipt of first Regulatory Approval, for commercial sale by Takeda in the Shared Territory, which Product was manufactured at the 500 liter scale. The milestone payment will be reduced by 25% if Cell Genesys fails to ship such Product (i) within 180 days of the date the FDA grants approval for the labeling and packaging for the Product in the event the label used by Cell Genesys precludes the use of the validation batches of the Product for commercial purposes; or (ii) within 120 days of the date the FDA grants approval for the labeling and packaging for the Product in the event the label used by Cell Genesys does not preclude the use of the validation batches of the Product for commercial purposes. The milestone payment will be reduced by an additional 25% for each subsequent 120 day-period following the date determined according to the preceding sentence in the event that Cell Genesys does not ship such Product prior to the expiration of each such subsequent 120 day-period. ] | [$40,000,000] |
| [Upon the first achievement of annual Net Sales in the Shared Territory of $750,000,000] | [$25,000,000] |
| [Upon the first achievement of annual Net Sales in the Shared Territory of $1,000,000,000] | [$50,000,000] |

**8.3 Development Milestone Payments**. Takeda shall make milestone payments to Cell Genesys based on achievement of certain milestone events for the Product as set forth in this Section 8.3, in partial consideration for the prior cost of developing the Product. Takeda shall pay to Cell Genesys the amounts set forth below within thirty (30) days after receipt of Cell Genesys' invoice following the achievement of the corresponding milestone event. Each milestone payment by Takeda to Cell Genesys hereunder shall be payable only once, regardless of the number of times achieved by the Products. Each such payment is nonrefundable and noncreditable against any other payments due hereunder.

| Milestone Event | Milestone Payment |
|---|---|
| [Upon acceptance by the FDA of the first MAA for the Product in the Field. | $20,000,000 |
| Upon the receipt of the first MAA approval by the FDA for the Product in the Field. | $60,000,000 |

| | |
|---|---|
| Upon acceptance of the first MAA for the Product in the Field in Europe. | $10,000,000 |
| Upon the earlier of (i) receipt of the first Regulatory Approval for the Product in the Field in Europe or (ii) first commercial sale of the Product in the Field in Europe. | $30,000,000 |
| Upon acceptance by the MHLW of the first MAA for the Product in the Field in Japan. | $5,000,000 |
| Upon the receipt of the first MAA approval by MHLW for the Product in the Field in Japan. | $15,000,000] |

For the avoidance of doubt, "acceptance" as used above shall mean acceptance for review of the applicable regulatory filing by the applicable Regulatory Authority.

**8.4 Royalties.**

**(a) Royalty Rates for Shared Territory**. Subject to Sections 8.4(c), 8.4(d) and 8.4(e) below, and during the applicable Royalty Term, Takeda shall pay to Cell Genesys a running royalty at the following incremental royalty rates, on aggregate, annual Net Sales of the Products in the Shared Territory.

| Net Sales in the Shared Territory | Royalty Rate |
|---|---|
| For that portion of annual Net Sales less than or equal to [$500,000,000] | 20% |
| For that portion of annual Net Sales greater than [$500,000,000] but less than or equal to [$750,000,000] | 30% |
| For that portion of annual Net Sales greater than [$750,000,000] but less than or equal to [$1,000,000,000] | 40% |
| For that portion of annual Net Sales greater than [$1,000,000,000] but less than or equal to [$1,250,000,000] | 50% |
| For that portion of annual Net Sales greater than [$1,250,000,000] but less than or equal to [$2,000,000,000] | 40% |
| For that portion of annual Net Sales greater than [$2,000,000,000] | 30% |

Takeda acknowledges that it will continue to enjoy substantial benefit from its license under, and the transfer to Takeda of certain elements of, the Cell Genesys Technology pursuant to this Agreement (including without limitation the Cell Genesys Know-How licensed to Takeda, and the regulatory data to be provided to Takeda pursuant to this Agreement) as well as from Takeda's own development of Takeda Technology derived from the practice of such license and Takeda's use of such Cell Genesys Technology, even after the expiration of all Cell Genesys Patents claiming the Product in a particular country of the Licensed Territory. In addition, Takeda acknowledges the application of a uniform royalty structure for the Shared Territory, throughout the Royalty Term, is more convenient to the Parties, facilitates the payment of royalties, and reduces accounting burdens on the Parties. Accordingly, the Parties have agreed to apply the same royalty rate in the Shared Territory throughout the Royalty Term, subject to Section 8.4(c).

**(b) Royalty Rates for ROW Territory**. Subject to Sections 8.4(c) and 8.4(e) below, and during the applicable Royalty Term, Takeda shall pay to Cell Genesys a running royalty equal to: (i) [twelve percent (12%)] of the annual Net Sales of the Products [in Japan], and (ii) [twenty percent (20%)] of the annual Net Sales of the Products in [each country of the ROW Territory other than Japan]. Takeda acknowledges that it will continue to enjoy substantial benefit from its license under, and the transfer to Takeda of certain elements of, the Cell Genesys Technology pursuant to this Agreement (including without limitation the Cell Genesys Know-How licensed to Takeda, and the regulatory data to be provided to Takeda pursuant to this Agreement) as well as from Takeda's own development of Takeda Technology derived from the practice of such license and Takeda's use of such Cell Genesys Technology, even after the expiration of all Cell Genesys Patents claiming the Product in a particular country of the ROW Territory. In addition, Takeda acknowledges the application of a uniform royalty structure throughout the Royalty Term is more convenient to the Parties, facilitates the payment of royalties, and reduces accounting burdens on the Parties. Accordingly, the Parties have agreed to apply the same royalty rate throughout the Royalty Term, subject to Section 8.4(c).

**(c) Reduction of Royalty Following Entry of Generic Product**. Following expiration of the last-to-expire Cell Genesys Patent or Joint Patent covering the Manufacture, use or sale of Products in a country of the Licensed Territory (including any Patent Term Extensions thereof), the royalty rates set forth in Section 8.4(a) and (b) for Net Sales in such country shall be (i) reduced by [50% at the end of the first to occur six (6) month period] during which one or more Third Parties sells a number of equivalent units of a Generic Version of the Product in such country of the Licensed Territory comprising, during such time period, [25% but equal to or less than 50%] or more of the aggregate combined number of equivalent units of such Product and such Generic Version(s) of such Product sold in such time period in such country (the "**Initial Threshold**"); and (ii) reduced by [75% at the end of the first to occur six (6) month period] during which one or more Third Parties sells a number of equivalent units of a Generic Version of the Product in such country of the Licensed Territory comprising, during such time period, [50% or more] of the aggregate combined number of equivalent units of such Product and such Generic Version(s) of such Product sold in such time period in such country. All such determinations of unit volume shall be based upon a mutually acceptable calculation method and using market share data provided by a reputable and mutually agreed upon provider, such as IMS Health. As used in this Section 8.4(c), "**Generic Version**" means, with respect to the Product, any [Third Party biological product that is approved by the Regulatory Authorities in such country of the Licensed

Territory as a "follow-on" biologic or "bio-similar" or equivalent version to the Product, in each case as defined in then-applicable Laws governing approval of biological products whose application for approval relies on data submitted on behalf of a reference drug, and administered in an cquivalcnt dosagc form and unit mode of administration]. At any time following introduction of the initial Generic Version of the Product in a country achieving a market share of at least the Initial Threshold and upon written notice of Takeda expressing concern regarding the continued commercial viability of the Product in such country, the Parties agree to negotiate in good faith a mutually acceptable strategy to address Takeda's concerns with a view toward preserving the historic economic balance and profit splits between the Parties.

**(d) Royalty Credit for Development Funding Payments**. Takeda will be entitled to credit the following amounts against royalties due pursuant to Section 8.4(a): (1) amounts paid by Takeda to Cell Genesys pursuant to Section 4.3(b)(i) and (2) actual amounts paid by Takeda for the performance of any Additional Studies that are necessary for obtaining the first Regulatory Approval by each or both of the FDA or EMEA. Such credit may be taken in any calendar quarter for which royalties are due for so long as payments made under such Sections have not been so recovered by Takeda; provided, that (i) for any individual calendar quarter, the amount of such credit may not reduce the royalties payable pursuant to this Section 8.4 by more than [50%] of the amount that would be due for such calendar quarter, absent such reduction, (ii) for any calendar year, the amount of such credit may not exceed [25%] of the total amounts paid by Takeda pursuant to Section 4.3(b)(i), taken in the aggregate, and (iii) for any amounts described in clause (2) above that are specific to a particular country or territory, such credit may not be taken until the First Commercial Sale of the Product in such country or territory. The amount of any credit remaining after the application of the foregoing limitations may be carried forward and applied to royalties payable for future calendar quarters.

**(e) Third Party Royalties**.

**(i)** Cell Genesys shall be solely responsible for the payment of any royalties, sublicense revenues, milestones or other payments due to Third Parties pursuant to the agreements listed on Exhibit B-3 arising from the Development and Commercialization of Products by Takeda, its Affiliates and their respective sublicensees in the Licensed Territory under this Agreement.

**(ii)** Except as set forth in clause (i) or (iii), or to the extent of any Claim for which Cell Genesys provides indemnification under Section 11.1, or as the Parties may otherwise agree in writing, Takeda shall bear any payments associated with any royalties owed to any Third Party for intellectual property that the Parties have mutually agreed in accordance with Section 9.6(c) is necessary or useful for the Development, Manufacture, storage, handling, use, promotion, sale, offer for sale, or importation of Products for sale in the Licensed Territory (the "**Third Party Royalties**").

**(iii)** Takeda may credit up to [fifty percent (50%)] of the amount of any Third Party Royalties paid by Takeda for Third Party intellectual property pursuant to clause (ii) above against royalties payable to Cell Genesys under Section 8.4(a) and (b). Takeda may take such credit during any calendar quarter for which royalties are payable hereunder; provided, that in no event will such credit reduce the royalties payable to Cell Genesys for such calendar

quarter by more than [fifty percent (50%)]. Any share of such Third Party Royalties that remains uncredited due to the application of such floor may be carried forward to subsequent calendar quarters.

**8.5 Royalty Reports and Payment**. By the tenth business day of each month, Takeda shall provide Cell Genesys with a report containing information for the Licensed Territory, to the extent reasonably available to Takeda for its internal reporting process purposes, with respect to all Net Sales of the Product for the applicable month, including the amount of gross sales of Product in the Licensed Territory, an itemized calculation of Net Sales in the Licensed Territory showing deductions, to the extent practicable, provided for in the definition of "Net Sales," a calculation of the royalty payment due on such sales, an accounting of the number of units and prices for Product sold. Within thirty (30) business days following the end of each calendar month, Takeda shall provide Cell Genesys with a report containing the following information for the applicable calendar month: the amount of gross sales of Product in the Licensed Territory, an itemized calculation of Net Sales in the Licensed Territory showing deductions, to the extent practicable, provided for in the definition of "Net Sales," a calculation of the royalty payment due on such sales, an accounting of the number of units and prices for Product sold, the exchange rate for each country in which Product was sold, the application of the reductions, if any, made in accordance with the terms of Section 8.4(d) or Section 8.4(e)(iii), and any information required by Cell Genesys for the purpose of calculating royalties and other amounts due under the Upstream Agreements. Within ten (10) business days following its receipt of such report, Cell Genesys shall review and record such information as it determines necessary under its internal financial reporting procedures. Within sixty (60) business days following the end of each calendar quarter, Takeda shall provide Cell Genesys with a report containing the information described above in respect of such calendar quarter for Cell Genesys' review and confirmation within two (2) business days from receipt. In the event that either party determines that the calculation of Net Sales for a calendar quarter deviates from the amounts previously reported to Cell Genesys for any reason (such as, on account of additional amounts collected or Product returns), Takeda and Cell Genesys shall reasonably cooperate to reconcile any such deviations to the extent necessary under applicable legal or financial reporting requirements. Within twenty (20) business days following Cell Genesys' written confirmation of the applicable quarterly report, Takeda shall pay all amounts due to Cell Genesys pursuant to Section 8.4 with respect to Net Sales by Takeda, its Affiliates and their respective sublicensees for such calendar quarter.

**8.6 Foreign Exchange**. The rate of exchange to be used in computing the amount of currency equivalent in Dollars owed to a Party under this Agreement shall be the monthly average exchange rate between each currency of origin and U.S. Dollars as reported by Bloomberg or an equivalent resource as agreed by the Parties.

**8.7 Payment Method; Late Payments**. All payments due to Cell Genesys hereunder shall be made in U.S. Dollars by wire transfer of immediately available funds into an account designated by Cell Genesys. If Cell Genesys does not receive payment of any sum due to it on or before the due date, simple interest shall thereafter accrue on the sum due to Cell Genesys until the date of payment at the per annum rate of [two percent (2%)] over the then-current prime rate quoted by Citibank in New York City or the maximum rate allowable by applicable Law, whichever is lower.

**8.8 Records; Audits.** Takeda will maintain complete and accurate records in sufficient detail to permit Cell Genesys to confirm the accuracy of the calculation of royalty and other payments under this Agreement. Upon reasonable prior notice, such records shall be available during regular business hours for a period of [three (3) years] from the end of the calendar year to which they pertain for examination at the expense of Cell Genesys, and not more often than once each calendar year, by an independent certified public accountant selected by Cell Genesys and reasonably acceptable to Takeda, for the sole purpose of verifying the accuracy of the financial reports furnished by Takeda pursuant to this Agreement. Takeda acknowledges that, pursuant to certain of the Upstream Agreements, Cell Genesys is required to permit its upstream licensors to conduct similar audits of Takeda's records. Takeda shall permit any such audit by such licensors; provided, that such audit is conducted in accordance with the terms of this Section 8.8; and provided, further, that any such audit shall not count towards the once per calendar year limit. Any such auditor shall not disclose Takeda's Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by Takeda or the amount of payments due by Takeda under this Agreement. Any amounts shown to be owed but unpaid shall be paid within thirty (30) days from the accountant's report, plus interest (as set forth in Section 8.7) from the original due date. Any amounts shown to have been overpaid shall be refunded within thirty (30) days from the accountant's report. Cell Genesys shall bear the full cost of such audit unless such audit discloses an underpayment by Takeda of more than five percent (5%) of the amount due, in which case Takeda shall bear the full cost of such audit.

**8.9 Taxes.**

**(a) Cooperation and Coordination.** The Parties acknowledge and agree that it is their mutual objective and intent to appropriately calculate, to the extent feasible and legal, taxes payable with respect to their collaborative efforts under this Agreement and that they shall use all commercially reasonable efforts to cooperate and coordinate with each other to achieve such objective.

**(b) Payment of Tax.** A Party receiving a payment pursuant to this Article 8 shall pay any and all taxes levied on such payment. If applicable Laws require that taxes be deducted and withheld from a payment made pursuant to this Article 8, the remitting Party shall (i) deduct those taxes from the payment; (ii) pay the taxes to the proper taxing authority; and (iii) send evidence of the obligation together with proof of payment to the other Party within sixty (60) days following that payment.

**(c) Tax Residence Certificate.** A Party (including any entity to which this Agreement may be assigned, as permitted under Section 15.5) receiving a payment pursuant to this Article 8 shall provide the remitting Party appropriate certification from relevant revenue authorities that such Party is a tax resident of that jurisdiction, if such receiving Party wishes to claim the benefits of an income tax treaty to which that jurisdiction is a party. Upon the receipt thereof, any deduction and withholding of taxes shall be made at the appropriate treaty tax rate.

**(d) Assessment.** Either Party may, at its own expense, protest any assessment, proposed assessment, or other claim by any Governmental Authority for any additional amount of taxes, interest or penalties or seek a refund of such amounts paid if permitted to do so by

applicable Law. The Parties shall cooperate with each other in any protest by providing records and such additional information as may reasonably be necessary for a Party to pursue such protest.

**8.10 Additional License Agreements.** Upon Cell Genesys' written request, the Parties shall negotiate in good faith the terms of and enter into one or more separate, written agreements (each, a **"License Agreement"**) pursuant to which Takeda shall grant Cell Genesys (i) [the right to use and license the Other Collaboration Data as provided for in Section 4.7, (ii) a right of reference to the Other Regulatory Materials as provided for in Section 5.6, and/or (iii) an exclusive or non-exclusive, royalty-bearing license under Takeda Patents as provided for in Section 2.2(b)], in each case (i) to (iii) solely for the purpose of Cell Genesys, its Affiliates or any Third Party licensees to develop, obtain and/or maintain regulatory approvals, commercialize, make, have made, use, sell, offer for sale, and import anywhere in the world GVAX products outside the Field. For clarity, in no event will Takeda be obligated to grant [an exclusive license under Takeda Patents] to Cell Genesys. The License Agreement(s) shall be negotiated in good faith by the Parties and shall contain commercially reasonable financial and other terms commonly found in license agreements for similar products for similar uses and consistent with the criteria set forth in Diligent Efforts. If the Parties do not agree upon the terms of a License Agreement in the case of a license for [non-exclusive rights to any Takeda Patents, Other Collaboration Data, or Other Regulatory Materials] described above within ninety (90) days after initiating negotiations, then either Party may submit the matter to binding mediation as described in Section 14.5.

## ARTICLE 9

## INTELLECTUAL PROPERTY MATTERS

**9.1 Ownership of Inventions**. Each Party shall own any inventions made solely by its own employees, agents, or independent contractors in the course of conducting its activities under this Agreement, together with all intellectual property rights therein ("**Sole Inventions**"). The Parties shall jointly own any inventions that are made jointly by employees, agents, or independent contractors of each Party in the course of performing activities under this Agreement, together with all intellectual property rights therein ("**Joint Inventions**"). Inventorship shall be determined in accordance with U.S. patent laws. Subject to the terms of this Agreement (including without limitation the licenses granted in Article 2 and Section 2.3), each Party may use and practice the Joint Inventions for any purpose and may assign, license or otherwise transfer or exploit its rights to the Joint Inventions to an Affiliate or Third Party, without the other Party's consent and without a duty of accounting to the other Party.

**9.2 Disclosure of Inventions**. Each Party shall promptly disclose to the other any invention disclosures, or other similar documents, submitted to it by its employees, agents or independent contractors describing inventions that are either Sole Inventions or Joint Inventions, and all Information relating to such inventions to the extent necessary for the preparation, filing and maintenance of any Patent with respect to such invention.

### 9.3 Prosecution of Patents.

**(a) Cell Genesys Patents.** Except as otherwise provided in this Section 9.3(a), as between the Parties, Cell Genesys shall have the sole right and authority to prepare, file, prosecute and maintain the Cell Genesys Patents on a worldwide basis; provided, that certain Cell Genesys Patents identified on Exhibit B-1 are filed, prosecuted and maintained by the applicable upstream licensor. Cell Genesys shall bear all costs of preparation, filing, prosecution and maintenance of Cell Genesys Patents in the Licensed Territory. Cell Genesys shall provide Takeda reasonable opportunity to review and comment on such efforts regarding such Cell Genesys Patents in the Licensed Territory, including by providing Takeda with a copy of material communications from any patent authority in the Licensed Territory regarding such Cell Genesys Patent, and by providing drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses. Subject to the terms of the Upstream Agreements, if Cell Genesys determines in its sole discretion to abandon or not maintain any Cell Genesys Patent(s) that is being prosecuted or maintained by Cell Genesys in the Licensed Territory, then Cell Genesys shall provide Takeda with written notice of such determination within a period of time reasonably necessary to allow Takeda to determine its interest in such Cell Genesys Patent(s). In the event Takeda provides written notice expressing its interest in obtaining such Cell Genesys Patent(s), Cell Genesys shall free of charge assign and transfer to Takeda the ownership of, and interest in, such Cell Genesys Patent(s) in the Licensed Territory, at Takeda's sole expense, and Cell Genesys shall cooperate with Takeda for assignment and transfer of such Cell Genesys Patent(s) in the Licensed Territory at Takeda's sole expense. Takeda shall thereafter bear all costs of preparation, filing, prosecution and maintenance of such assigned and transferred Patents. In the event that Takeda decides to abandon or not maintain any such Patent(s), Takeda shall promptly provide Cell Genesys with written notice of such decision.

**(b) Takeda Patents.** Except as otherwise provided in this Section 9.3(b), Takeda shall have the sole right and authority to prepare, file, prosecute and maintain the Takeda Patents on a worldwide basis at its own expense. Takeda shall provide Cell Genesys reasonable opportunity to review and comment on such efforts regarding such Takeda Patents in the Licensed Territory, including by providing Cell Genesys with a copy of material communications from any patent authority regarding such Takeda Patents in the Licensed Territory, and by providing drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses. If Takeda determines in its sole discretion to abandon or not maintain any Takeda Patents in the Licensed Territory, then Takeda shall provide Cell Genesys with written notice of such determination within a period of time reasonably necessary to allow Cell Genesys to determine its interest in such Takeda Patent(s). In the event Cell Genesys provides written notice expressing its interest in obtaining such Takeda Patent(s), Takeda shall free of charge assign and transfer to Cell Genesys the ownership of, and interest in, such Takeda Patent(s) in the applicable jurisdiction on behalf of Takeda at Cell Genesys' sole expense, and Takeda shall cooperate with Cell Genesys for the assignment and transfer of such Takeda Patent(s) at Cell Genesys' sole expense. Cell Genesys shall thereafter bear all costs of preparation, filing, prosecution and maintenance of such assigned and transferred Patent(s). Cell Genesys shall provide Takeda reasonable opportunity to review and comment on such efforts regarding such Patents, to the extent such Patents correspond to Patents being prosecuted or maintained by, or issued to, Takeda anywhere in the world, including by providing Takeda with a copy of material communications from any patent authority in the Licensed Territory regarding such Patent(s), and

by providing drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses. In the event that Cell Genesys decides to abandon or not maintain any such Patent(s), Cell Genesys shall promptly provide Takeda with written notice of such decision.

**(c) Joint Patents.** Except as otherwise provided in this Section 9.3(c), Takeda shall have the primary right and authority to prepare, file, prosecute and maintain the Patents included in the Joint Inventions ("**Joint Patents**") on a worldwide basis. Cell Genesys and Takeda shall share equally all costs of preparation, filing, prosecution and maintenance of the Joint Patents. Takeda shall provide Cell Genesys with the reasonable opportunity (and unless necessary to avoid a material adverse impact on such Joint Patents, at least thirty (30) days) to review and comment on such efforts regarding such Joint Patent, including by providing Cell Genesys with a copy of material communications from any patent authority in such country(ies) regarding such Joint Patent, and by providing drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses, and Takeda shall give due consideration to any reasonable comments made by Cell Genesys. If Takeda determines in its sole discretion to abandon or not maintain any Joint Patent(s) in any country(ies) of the world, then Takeda shall provide Cell Genesys with written notice of such determination within a period of time reasonably necessary to allow Cell Genesys to determine its interest in such Joint Patent(s). In the event Cell Genesys provides written notice expressing its interest in obtaining such Joint Patent(s), Takeda shall free of charge assign and transfer to Cell Genesys the ownership of, and interest in, such Joint Patent(s) in such country(ies), at Cell Genesys' sole expense, and Takeda shall cooperate with Cell Genesys for assignment and transfer of such Joint Patent(s) in such country.

**(d) Cooperation in Prosecution**. Each Party shall provide the other Party all reasonable assistance and cooperation in the Patent prosecution efforts provided above in this Section 9.3, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution, as well as further actions as set forth below.

**(i)** The Parties shall respectively prepare, file, maintain and prosecute the Cell Genesys Patents, Joint Patents, and Takeda Patents as set forth in this Section 9.3, subject to the terms of the Upstream Agreements. As used herein, "prosecution" of such Patents shall include, without limitation, all communication and other interaction with any patent office or patent authority having jurisdiction over a patent application in connection with pre-grant proceedings. Post-grant proceedings shall be governed by Section 9.8(b).

**(ii)** All communications between the Parties relating to the preparation, filing, prosecution or maintenance of the Cell Genesys Patents and Takeda Patents, including copies of any draft or final documents or any communications received from or sent to patent offices or patenting authorities with respect to such Patents, shall be considered Confidential Information and subject to the confidentiality provisions of Article 12.

**(iii)** Assignments in the Cell Genesys Patents and Takeda Patents shall be effected as follows: (1) employees or agents of Takeda that are named as inventors on the Takeda Patents shall assign their interest in such Patents to Takeda; (2) employees or agents of

Cell Genesys that are named as inventors on the Cell Genesys Patents shall assign their interest in such Patents to Cell Genesys; and (3) Takeda and Cell Genesys shall assign their respective ownership interest in the Takeda Patents and Cell Genesys Patents, as applicable, to the other Party pursuant to Article 9. Any such assignment shall be subject to the rights and interests of each Party as set forth in Article 2.

**9.4 Patent Term Extensions in the Licensed Territory**. The JSC will discuss and recommend for which, if any, of the Patents within the Cell Genesys Patents, Joint Patents, and Takeda Patents in the Licensed Territory the Parties should seek Patent Term Extensions in the Licensed Territory. Cell Genesys, in the case of the Cell Genesys Patents and Joint Patents, and Takeda in the case of the Takeda Patents, shall have the final decision-making authority with respect to applying for any such Patent Term Extensions in the Licensed Territory, and will act with reasonable promptness in light of the development stage of Products to apply for any such Patent Term Extensions, where it so elects; provided, however, that if in a particular country or jurisdiction in the Licensed Territory only one such Patent can obtain a Patent Term Extension, then the Parties will consult in good faith to determine which such Patent should be the subject of efforts to obtain a Patent Term Extension, and in any event Cell Genesys' decision on such matter will control in the case of a disagreement. The Party that does not apply for an extension hereunder will cooperate fully with the other Party in making such filings or actions, for example and without limitation, making available all required regulatory data and information and executing any required authorizations to apply for such Patent Term Extension. All expenses incurred in connection with activities of each Party with respect to the Patent(s) for which such Party seeks Patent Term Extensions pursuant to this Section 9.4 shall be entirely borne by such Party.

**9.5 Infringement of Patents by Third Parties**.

**(a) Notification**. Each Party shall promptly notify the other Party in writing of any existing or threatened infringement of the Cell Genesys Patents, Joint Patents or Takeda Patents of which it becomes aware, and shall provide all evidence in such Party's possession demonstrating such infringement.

**(b) Infringement of Cell Genesys Patents or Joint Patents**.

**(i)** If a Third Party infringes any Cell Genesys Patent or Joint Patent in the Licensed Territory by making, using, importing, offering for sale or selling the Product or a competitive product (a "**Product Infringement**"), each Party shall share with the other Party all Information available to it regarding such alleged infringement. Takeda shall have the first right, but not the obligation, to bring an appropriate suit or other action against any person or entity engaged in such Product Infringement in the Licensed Territory, subject to Section 9.5(b)(ii) through 9.5(b)(v), below.

**(ii)** Takeda shall have a period of [ninety (90)] days after the first notice under 9.5(a) to elect to enforce such Cell Genesys Patent or Joint Patent against such Product Infringement. In the event Takeda does not so elect, Takeda shall so notify Cell Genesys in writing, and Cell Genesys shall have the right to commence a suit or take action to enforce the applicable Patent against such Third Party perpetrating such Product Infringement in

the Licensed Territory at its own cost and expense. If one Party elects to bring suit or take action against the Product Infringement, then the other Party shall have the right, prior to commencement of the trial, suit or action, to join any such suit or action.

(iii) Each Party shall provide to the Party enforcing any such rights under this Section 9.5(b) reasonable assistance in such enforcement, at such enforcing Party's request and expense, including joining such action as a party plaintiff if required by applicable Law to pursue such action. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts, shall reasonably consider the other Party's comments on any such efforts, and shall seek consent of the other Party in any important aspects of such enforcement including, without limitation, determination of litigation strategy, filing of important papers to the competent court, which shall not be unreasonably withheld or delayed.

(iv) Each Party shall bear all of its own internal costs incurred in connection with its activities under this Section 9.5(b); provided, that in the event that the Parties are joined in suit or action against the Product Infringement and represented by the same outside counsel, then the Parties shall share equally in the external costs and expenses for such action.

(v) The Party not bringing an action with respect to Product Infringement in the Licensed Territory under this Section 9.5(b) shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the Party bringing such action.

(c) **Infringement of Takeda Patents**. For any and all infringement of any Takeda Patent that claims a Sole Invention anywhere in the Licensed Territory, Takeda shall have the sole and exclusive right, but not the obligation, to bring, at Takeda's expense and in its sole control, an appropriate suit or other action against any person or entity engaged in such infringement of the Takeda Patent.

(d) **Settlement**. Takeda shall not settle any claim, suit or action that it brought under this Section 9.5 involving Cell Genesys Patents or Joint Patents without the prior written consent of Cell Genesys, which consent shall not be unreasonably withheld or delayed.

(e) **Allocation of Proceeds**. If either Party recovers monetary damages from any Third Party in a suit or action brought under Sections 9.5(b), 9.5(c), or 9.8(b), whether such damages result from the infringement of Cell Genesys Patents, Joint Patents or Takeda Patents, such recovery shall be allocated first to the reimbursement of any expenses incurred by the Parties in such litigation (including, for this purpose, a reasonable allocation of expenses of internal counsel), and any remaining amounts shall be split as follows: (i) [if such suit or action is initiated or defended by Takeda, such amounts shall be retained by Takeda and treated as Net Sales for purposes of the royalties due to Cell Genesys under this Agreement], or (ii) [if such suit or action was initiated or defended by Cell Genesys, such amounts shall be allocated 70% to Cell Genesys and 30% to Takeda].

**9.6 Infringement of Third Party Rights in the Licensed Territory.**

(a) **Notice**. If any Product used or sold by either Party, its Affiliates, licensees or sublicensees becomes the subject of a Third Party's claim or assertion of infringement of a

Patent granted by a jurisdiction within the Licensed Territory, the Party first having notice of the claim or assertion shall promptly notify the other Party, the Parties shall agree on and enter into an "identity of interest agreement" wherein such Parties agree to their shared, mutual interest in the outcome of such potential dispute, and thereafter, the Parties shall promptly meet to consider the claim or assertion and the appropriate course of action.

**(b) Defense.** Takeda shall have the first right, but not the obligation, to defend any such Third Party claim or assertion of infringement of a Patent as described in Section 9.6(a) above, at Takeda's expense. If Takeda does not commence actions to defend such claim within [thirty (30) days] after it receives notice thereof (or within [thirty (30) days] after it should have given notice thereof to Cell Genesys as required by Section 9.6(a)), then to the extent allowed by Laws, Cell Genesys shall have the right, but not the obligation, to control the defense of such claim by counsel of its choice, at Cell Genesys' expense. The non-defending Party shall reasonably cooperate with the Party conducting the defense of the claim or assertion, including if required to conduct such defense, furnishing a power of attorney.

**(c) Settlement; Licenses.** Neither Party shall enter into any settlement of any claim described in this Section 9.6 that [affects the other Party's rights or interests without such other Party's written consent, which consent shall not be unreasonably withheld or delayed]. Each Party shall have the right to [decline to defend or to tender defense of any such claim] to the other Party upon reasonable notice, including without limitation if the other Party fails to agree to a settlement that such Party proposes. If a Party desires to take a license under any applicable Third Party intellectual property rights for the purpose of Developing or Commercializing the Product in the Field, then [such Party shall submit the terms of such license to the JSC for review and approval]. Any such license agreement will require the applicable Third Party to [grant licenses to both Takeda and Cell Genesys] for use in the Licensed Territory, will contain [a release of any liabilities accrued] prior to the effective date of such license agreement, and will be subject to the [mutual agreement of the Parties' representatives to the JSC (notwithstanding any tie-breaking mechanisms described in Section 14.2)].

**9.7 Patent Marking.** Takeda (or its Affiliate, sublicensee or distributor) shall mark Products marketed and sold by Takeda (or its Affiliate, sublicensee or distributor) hereunder with appropriate patent numbers or indicia at Cell Genesys' request and in accordance with the terms of the Upstream Agreements; provided, however, that Takeda shall only be required to so mark such Products to the extent such markings or such notices would impact recoveries of damages or equitable remedies available under applicable law with respect to infringements of patents in the Licensed Territory.

**9.8 Patent Oppositions and Other Proceedings.**

**(a) Third-Party Patent Rights.** If either Party desires to bring an opposition, action for declaratory judgment, nullity action, interference, declaration for non-infringement, reexamination or other attack upon the validity, title or enforceability of a Patent owned or controlled by a Third Party and having one or more claims that covers the Product, or the use, sale, offer for sale or importation of the Product (except insofar as such action is a counterclaim to or defense of, or accompanies a defense of, a Third Party's claim or assertion of infringement under Section 9.6, in which case the provisions of Section 9.6 shall govern), such Party shall so

notify the other Party and the Parties shall promptly confer to determine whether to bring such action or the manner in which to settle such action. Takeda shall have the exclusive right, but not the obligation, to bring at its own expense and in its sole control such action in the Licensed Territory. If Takeda does not bring such an action in the Licensed Territory, within [ninety (90)] days of notification thereof pursuant to this Section 9.8(a) (or earlier, if required by the nature of the proceeding), then Cell Genesys shall have the right, but not the obligation, to bring, at Cell Genesys' sole expense, such action. The Party not bringing an action under this Section 9.8(a) shall be entitled to separate representation in such proceeding by counsel of its own choice and at its own expense, and shall cooperate fully with the Party bringing such action. Any awards or amounts received in bringing any such action shall be first allocated to reimburse the initiating Party's expenses in such action, and any remaining amounts shall be retained by such Party.

**(b) Parties' Patent Rights**. If any Cell Genesys Patent or Takeda Patent becomes the subject of any proceeding commenced by a Third Party within the Licensed Territory in connection with an opposition, reexamination request, action for declaratory judgment, nullity action, interference or other attack upon the validity, title or enforceability thereof (except insofar as such action is a counterclaim to or defense of, or accompanies a defense of, an action for infringement against a Third Party under Section 9.5, in which case the provisions of Section 9.5 shall govern), then the Party responsible for filing, preparing, prosecuting and maintaining such Patent as set forth in Section 9.3 hereof, shall control such defense at its own cost and expense. The controlling Party shall permit the non-controlling Party to participate in the proceeding to the extent permissible under applicable Law, and to be represented by its own counsel in such proceeding, at the non-controlling Party's expense. If either Party decides that it does not wish to defend against such action, then the other Party shall have a backup right to assume defense of such Third-Party action at its own expense. Any awards or amounts received in defending any such Third-Party action shall be allocated between the Parties as provided in Section 9.5(e).

**(c) Patent Challenge**. Cell Genesys will be permitted to terminate this Agreement upon written notice to Takeda, effective upon receipt, if Takeda or any of its Affiliates, directly or indirectly: (i) initiate or request an interference, opposition proceeding or request for ex parte or inter-parties reexamination with respect to any Cell Genesys Patent, (ii) make, file or maintain any claim, demand, lawsuit or cause of action to challenge the validity or enforceability of any an Cell Genesys Patent, or (ii) oppose any Patent Term Extension with respect to any Cell Genesys Patent (each, a "**Patent Challenge**"). Takeda will include provisions in all agreements granting sublicenses under Takeda's rights hereunder providing that if the sublicensee or any of its Affiliates undertake a Patent Challenge, Takeda may terminate all sublicenses under the Cell Genesys Patents granted to such sublicensee. If a sublicensee (or an Affiliate of such sublicensee) undertakes a Patent Challenge, then Takeda upon receipt of notice thereof from Cell Genesys, will terminate all sublicenses under the Cell Genesys Patents granted to such sublicensee in the applicable sublicense agreement. If Takeda fails to so terminate such sublicenses, then Cell Genesys may terminate this Agreement upon written notice to Takeda, effective upon receipt.

## ARTICLE 10

## REPRESENTATIONS AND WARRANTIES

**10.1 Mutual Representations and Warranties.** Each Party hereby represents, warrants, and covenants (as applicable) to the other Party as follows:

**(a) Corporate Existence and Power.** As of the Effective Date, it is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including, without limitation, the right to grant the licenses granted by it hereunder.

**(b) Authority and Binding Agreement.** As of the Effective Date, (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder; and (iii) the Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

**(c) No Conflict; Covenant.** It is not a party to any agreement that would materially prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under the Agreement.

**(d) No Debarment.** In the course of the development of Products, each Party shall not use, during the Term, any employee or consultant who has been debarred by any Regulatory Authority, or, to the best of such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority.

**(e) Conduct of Activities.** Each Party's Development of the Product in the Field for the Licensed Territory shall be conducted in a manner consistent with Diligent Efforts and with the following: (i) in the case of Takeda, to its Best Knowledge at the time of initiating any activity in connection with such Development, not adversely impacting Cell Genesys' or its Third Party partner's own development or commercialization efforts for GVAX products outside the Field, provided that the foregoing shall not obligate Takeda to take any action that would materially and adversely impact the value of the Product in the Shared Territory in the Field, and (ii) in the case of Cell Genesys, not adversely impacting Takeda's or its sublicensees' Development or Commercialization efforts for Products in the Licensed Territory for the Field. Nothing contained in this Section 10.1(e) shall be construed as imposing a non-compete obligation on either of the Parties.

**10.2 Additional Representations and Warranties of Cell Genesys.** Cell Genesys represents and warrants to Takeda as follows:

**(a) Non-Infringement of Cell Genesys Technology by Third Parties.** As of the Effective Date, to Cell Genesys' Best Knowledge, there are no ongoing activities by Third

Parties that would constitute infringement or misappropriation of the Cell Genesys Technology within the Licensed Territory.

**(b) Non-Infringement of Third Party Rights**. As of the Effective Date, to Cell Genesys' Best Knowledge, none of the manufacture, use or the sale of the Product (as defined in Section 1.69(a)) in the Licensed Territory infringes any valid enforceable claim of an existing Patent owned by a Third Party.

**(c) Non-Claims of Third Party Rights**. As of the Effective Date, Cell Genesys has not received any verbal or written claim or demand of any person or entity that the manufacture, use, or sale of the Product (as defined in Section 1.69(a)) in the Licensed Territory infringes a Third Party Patent.

**(d) Cell Genesys Patents Not Invalid or Unenforceable**. As of the Effective Date, the Cell Genesys Patents exist, and the issued patents in the Cell Genesys Patents have not been held invalid or unenforceable, in whole or in part, by a court or other governmental agency of competent jurisdiction;

**(e) No Encumbrances**. As of the Effective Date, all Patents and all know-how owned by Cell Genesys or licensed from a Third Party that are necessary or useful to Develop, Commercialize and Distribute Product (as defined in Section 1.69(a)) in the Field in the Licensed Territory are (i) free and clear of any encumbrance, lien, or claim of ownership or license by any Third Party, including but not limited to [under its previous collaboration with Japan Tobacco Inc.]; provided that Patents and know-how owned by Cell Genesys or licensed from a Third Party are subject to a [non-exclusive research license granted to Medarex, Inc. solely for the use of GVAX during the term of the agreement between Medarex, Inc. and Cell Genesys to perform Medarex Inc.'s research obligations under such agreement in support of clinical trial G-0016: "A Phase 1 Dose Escalation Trial of MDX-010 in Combination with CG1940 and CG8711 in Patients with Metastatic Hormone-Refractory Prostate Cancer" (including any amendment thereto pending as of the Effective Date)] and for no other purpose, including without limitation any commercial purpose or other research unrelated to the [G-0016 clinical trial], and (ii) licensed to Takeda as provided in Article 2; provided that Patents and know-how licensed from Third Parties are subject to the terms of the Upstream Agreements;

**(f) Disclosure**. Prior to the Effective Date, Cell Genesys made available to Takeda, or provided Takeda with, copies of all information with respect to the Product (as defined in Section 1.69(a)) as requested by Takeda in writing. In addition, as of the Effective Date Cell Genesys has disclosed to Takeda any material information known to Cell Genesys as of such date with respect to (i) the safety of the Product (as defined in Section 1.69(a)), (ii) the efficacy of such Product (as defined in Section 1.69(a)), (iii) any then-existing circumstance which would be reasonably likely to prohibit or prevent the Development, Manufacturing and/or Commercialization of the Product (as defined in Section 1.69(a)) in the Licensed Territory;

**(g) Non-Action or Claim**. As of the Effective Date, to Cell Genesys' Best Knowledge, there are no actual, pending, alleged or threatened adverse actions, suits, claims, interferences or formal governmental investigations involving the Product (as defined in Section 1.69(a)) and/or the Cell Genesys Technology relating to the Product (as defined in Section

1.69(a)) by or against Cell Genesys or any of its Affiliates in or before any court, governmental or regulatory authority. In particular, as of the Effective Date, to its Best Knowledge, there is no pending or threatened product liability action involving the Product (as defined in Section 1.69(a)). As of the Effective Date, to Cell Genesys' Best Knowledge, there are no claims, judgments or settlements against or owed by Cell Genesys relating to the Cell Genesys Technology or the Product (as defined in Section 1.69(a)).

**(h) Regulatory Materials and Studies.** To Cell Genesys' Best Knowledge, all Regulatory Materials Controlled by Cell Genesys in existence as of the Effective Date and to which Takeda has rights of use or reference hereunder, including the Regulatory Materials described in Section 5.1, have been prepared, maintained and retained in accordance with applicable Laws. All preclinical and clinical studies conducted with respect to the Product (as defined in Section 1.69(a)) in connection with the preparation of such Regulatory Materials, including such studies from which the data described in Section 5.1 are derived, have been conducted substantially in accordance with applicable Laws by persons with appropriate education, knowledge and experience. As of the Effective Date, Cell Genesys has not been debarred and is not subject to debarment, in each case pursuant to Section 306 of the FD&C Act or any similar law or regulation in any jurisdiction outside the Shared Territory.

**(i) Upstream Agreements**. As of the Effective Date, to Cell Genesys' Best Knowledge, Cell Genesys is not in breach of any of the Upstream Agreements.

**10.3 Disclaimer**. Takeda understands that the Products are the subject of ongoing clinical research and development and that Cell Genesys cannot assure the safety or usefulness of Products. In addition, Cell Genesys makes no warranties except as set forth in this Article 10 concerning the Cell Genesys Technology.

**10.4 No Other Representations or Warranties**. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, IS MADE OR GIVEN BY OR ON BEHALF OF A PARTY. ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

## ARTICLE 11

## INDEMNIFICATION

**11.1 Indemnification by Cell Genesys**. Cell Genesys shall defend, indemnify, and hold Takeda and Takeda's officers, directors, employees, and agents (the **"Takeda Indemnitees"**) harmless from and against any and all Third Party claims, suits, proceedings, damages, expenses (including court costs and reasonable attorneys' fees and expenses), and recoveries (collectively, **"Claims"**) to the extent that such Claims arise out of, are based on, or result from (a) the Development, Manufacture, storage, handling, use, promotion, sale, offer for sale, and importation of Products by or on behalf of Cell Genesys or its Affiliates, distributors

(other than Takeda), sublicensees (other than Takeda), or contract manufacturers (the **"Cell Genesys Group"**) (unless and to the extent such liability for Manufacturing activities are covered by separate indemnification pursuant to the Supply Agreement, which in such event will control), or (b) the breach of any representation, warranty or covenant of Cell Genesys in this Agreement, or (c) the willful misconduct or negligent acts of Cell Genesys, its Affiliates, or the officers, directors, employees, or agents of Cell Genesys or its Affiliates. The foregoing indemnity obligation shall not apply to the extent that (i) the Takeda Indemnitees fail to comply with the indemnification procedures set forth in Section 11.3 and Cell Genesys' defense of the relevant Claims is prejudiced by such failure, or (ii) any Claim arises from, is based on, or results from any activity for which Takeda is obligated to indemnify the Cell Genesys Indemnitees under Section 11.2.

**11.2 Indemnification by Takeda**. Takeda shall defend, indemnify, and hold Cell Genesys and Cell Genesys' officers, directors, employees, and agents (the "**Cell Genesys Indemnitees**") harmless from and against any and all Claims to the extent that such Claims arise out of, are based on, or result from (a) the Development, storage, handling, Distribution, use, Manufacture (unless and to the extent liability for Manufacturing activities are covered by separate indemnification pursuant to the Supply Agreement, which in such event will control) promotion, sale, offer for sale, and importation of Products by Takeda or its Affiliates, or its or their sublicensees, or distributors, or (b) the breach of any representation, warranty or covenant of Takeda set forth in this Agreement, or (c) the willful misconduct or negligent acts of Takeda or its Affiliates, or the officers, directors, employees, or agents of Takeda or its Affiliates. The foregoing indemnity obligation shall not apply to the extent that (i) the Cell Genesys Indemnitees fail to comply with the indemnification procedures set forth in Section 11.3 and Takeda's defense of the relevant Claims is prejudiced by such failure, or (ii) any Claim arises from, is based on, or results from any activity for which Cell Genesys is obligated to indemnify the Takeda Indemnitees under Section 11.1.

**11.3 Indemnification Procedures**. The Party claiming indemnity under this Article 11 (the "**Indemnified Party**") shall give written notice to the Party from whom indemnity is being sought (the "**Indemnifying Party**") in a reasonably timely manner after learning of such Claim. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; provided, however, the Indemnifying Party shall have the right to assume and conduct the defense of the claim with counsel of its choice. The Indemnifying Party shall not settle any claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, unless the settlement involves only the payment of money. So long as the Indemnifying Party is actively defending the claim in good faith, the Indemnified Party shall not settle any such claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the claim as provided above, (a) the Indemnified Party may defend against, and consent to the entry of any judgment or enter into any settlement with respect to the claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnifying Party will remain responsible to indemnify the Indemnified Party as provided in this Article 11.

**11.4 Limitation of Liability**. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 11.4 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 11.1 OR 11.2, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 12.

**11.5 Insurance**. Each Party shall procure and maintain insurance, including product liability insurance, adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated at all times during which any Product is being clinically tested in human subjects or commercially distributed or sold by such Party. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 11. Each Party shall provide the other Party with written evidence of such insurance upon request. Each Party shall provide the other Party with written notice at least thirty (30) days prior to the cancellation, non-renewal or material change in such insurance or self-insurance which materially adversely affects the rights of the other Party hereunder.

## ARTICLE 12

## CONFIDENTIALITY

**12.1 Confidentiality**. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties during a period that is the longer of (i) the Term, or (ii) [fifteen (15)] years from the Effective Date, each Party agrees that it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement any Confidential Information furnished to it by the other Party pursuant to this Agreement except for that portion of such information or materials that the receiving Party can demonstrate by competent written proof:

**(a)** was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the other Party;

**(b)** was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

**(c)** became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

**(d)** was disclosed to the receiving Party or its Affiliate by a Third Party who has a legal right to make such disclosure; or

**(e)** was independently discovered or developed by the receiving Party or its Affiliate without the aid, application, or use of the disclosing Party's Confidential Information, as evidenced by a contemporaneous writing.

**12.2 Authorized Disclosure**. Each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following situations:

**(a)** regulatory filings and other filings with Governmental Authorities, including filings with the Securities and Exchange Commission or other relevant exchange on which such Party is listed;

**(b)** prosecuting or defending litigation;

**(c)** complying with applicable Laws;

**(d)** disclosure to its employees, agents, consultants, and any bona fide Third Party potential (sub)-licensees (including potential Third Party licensees or collaborators) only on a need-to-know basis and solely as necessary in connection with the performance of or as otherwise contemplated by this Agreement, provided that in each case the recipient of such Confidential Information must agree to be bound by similar obligations of confidentiality and non-use at least as equivalent in scope as those set forth in this Article 12 prior to any such disclosure; and

**(e)** disclosure of the material terms of this Agreement to any bona fide potential investor, investment banker, acquiror, merger partner, licensees, sublicensees or other potential or actual financial or commercial partner; provided that in connection with such disclosure, the disclosing Party shall use all reasonable efforts to inform each recipient of the confidential nature of such Confidential Information and cause each recipient of such Confidential Information to treat such Confidential Information as confidential.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to clause (a) through (c) of this Section 12.2, it will, except where impracticable, give reasonable advance notice to the other Party of such disclosure and use diligent efforts to secure confidential treatment of such information. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder. Each Party will be responsible for any acts or omissions of any Third Party to which such Party discloses Confidential Information in accordance with this Section 12.2.

**12.3 Publicity**.

**(a)** The Parties shall make a joint public announcement of the execution of this Agreement in the form attached as Exhibit F, which shall be issued at a time to be mutually agreed by the Parties.

**(b)** Neither Party shall issue any additional press release or other publicity materials, or make any public presentation with respect to the terms or conditions of, this Agreement or the programs or efforts being conducted by the other Party hereunder, in each case

without the prior written consent of the other Party. This restriction shall not apply to any future disclosures required by law or regulation, including as may be required in connection with any filings made with, or by the requirements of the securities exchange on which such Party's securities are traded; provided, that the disclosing Party (i) use all reasonable efforts to inform the other Party at least three (3) business days prior to making any such disclosures and cooperate with the other Party in seeking a protective order or other appropriate remedy (including redaction) and (ii) whenever possible, request confidential treatment of such information. In addition, where required by law or by the regulations of the applicable securities exchange upon which a Party may be listed, such Party shall have the right to make a press release announcing the achievement of each milestone under this Agreement as it is achieved, and the achievements of Regulatory Approvals in the Licensed Territory as they occur, subject only to the review procedure set forth in the preceding sentence. In relation to the other Party's review of such an announcement, such other Party may make specific, reasonable comments on such proposed press release within the prescribed time for commentary, but shall not withhold its consent to disclosure of the information that the relevant milestone has been achieved and triggered a payment hereunder. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement that has already been publicly disclosed by such Party, or by the other Party, in accordance with this Section 12.3.

## ARTICLE 13

## TERM AND TERMINATION

**13.1 Term**. This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Article 13, shall remain in effect, on a Product-by-Product basis and on a country-by-country basis, until the expiration of the Royalty Term of such Product in such country.

**13.2 Early Termination**.

**(a) Unilateral Termination by Takeda Prior to First Commercial Sale.** Prior to First Commercial Sale in the Licensed Territory, Takeda shall have the right to terminate this Agreement, for any or no reason upon [ninety (90) days'] written notice, either (i) in its entirety, or (ii) country by country.

**(b) Unilateral Termination by Takeda After First Commercial Sale**. Effective only after First Commercial Sale, Takeda shall have the right to terminate this Agreement, for any or no reason, upon [one hundred eighty (180) days'] written notice to Cell Genesys, either (i) in its entirety, or (ii) country by country; provided, that no termination under this Section 13.2(b) shall become effective prior to the second anniversary of such First Commercial Sale(s) in the relevant country(ies).

**(c) Unilateral Termination by Takeda for Lack of Commercial Viability**. Effective only after the First Commercial Sale, Takeda shall have the right to terminate this Agreement in its entirety or country by country upon [ninety (90) days'] written notice to Cell Genesys, if Takeda determines in good faith that the continued Development and Commercialization of the Product under this Agreement in its entirety or country by country is

and will not be commercially viable or profitable; provided, that no such termination shall become effective prior to (i) the first anniversary of the First Commercial Sale in any country in the Licensed Territory, or (ii) six months following the First Commercial Sale in any country in the Licensed Territory in the case where an applicable Law of any Governmental Authority results in a materially adverse market environment for the Commercialization of the Product which is not likely to abate before the first anniversary of the First Commercial Sale in any country in the Licensed Territory. The determination of profitability and commercial viability under this Section 13.2(c) shall be made on the basis of Diligent Efforts and taking into account financial projections suitable to support Commercialization of the Product on the terms set forth in this Agreement.

**13.3 Termination for Breach**. Cell Genesys shall have the right to terminate this Agreement upon written notice to Takeda for material breach by Takeda of its obligations under this Agreement if, after receiving written notice identifying such material breach, Takeda fails to cure such material breach within [sixty (60) days] from the date of such notice (or within [thirty (30) days'] notice in the event such breach is solely based upon Takeda's failure to pay any undisputed amounts due Cell Genesys hereunder). Takeda shall have the right to terminate this Agreement upon written notice to Cell Genesys for material breach by Cell Genesys of its obligations under this Agreement if, after receiving written notice identifying such material breach, Cell Genesys fails to cure such breach within [sixty (60) days] from the date of such notice (or within [thirty (30) days'] notice in the event such breach is solely based upon Cell Genesys' failure to pay or credit any undisputed amounts due Takeda hereunder).

**13.4 Termination for Safety**. Takeda shall have the right to terminate this Agreement with at least [thirty (30) days] written notice at any time (i) if, subject to Section 14.3(b), [senior executives responsible for Takeda's Pharmacoviligence and Clinical Science functions] determine in good faith and in consideration of Diligent Efforts that the risk/benefit profile of the Product is such that the Product cannot continue to be Developed or administered to patients safely (and not for commercial reasons), or (ii) upon the occurrence of serious adverse events related to the use of Product that cause Takeda to reasonably conclude that the continued use of Product by patients will result in patients being exposed to a product in which the risks outweigh the benefits. For clarity, the pursuit of discussions under Section 14.3(b) shall not eliminate Takeda's termination right under this Section 13.4. Upon any such termination, (x) the Parties shall reasonably cooperate with each other in the wind-down and/or, if applicable, transition of all the activities from Takeda to Cell Genesys, or such Third Party designated by Cell Genesys, (y) the provisions of Section 13.5(a), (b), (d), (e), (f) and (g) shall apply, and (z) the provisions of Section 5.7(d) shall continue to apply with respect to the regulatory reporting obligations of either Party.

**13.5 Effect of Termination for Takeda**. The following provisions shall apply if (i) Takeda terminates this Agreement in its entirety or with respect to certain countries pursuant to Section 13.2(a), (b), or (c), or (ii) Cell Genesys terminates this Agreement in its entirety under Section 13.3 due to Takeda's material uncured breach, and following a final, non-appealable judgment pursuant to Section 14.3 of Takeda's material breach of this Agreement (unless Takeda in writing does not dispute Cell Genesys' determination of Takeda's material breach).

**(a) Outstanding Obligations.** Takeda shall be responsible for any outstanding payment obligations of Takeda that existed or accrued prior to the effective date of termination with respect to the terminated countries.

**(b) Product Supply Costs.** Takeda shall be responsible for any reasonable and non-cancelable costs incurred by Cell Genesys prior to the effective date of termination in connection with its supply of Products to Takeda under this Agreement or the Supply Agreement, including any unusable or obsolete safety stock of the Product required to be Manufactured and maintained by Cell Genesys.

**(c) Development Expenses.** Takeda shall be responsible for any reasonable expenses incurred by Cell Genesys for (i) to the extent any such individual Development activity cannot reasonably be terminated early, the conduct and completion of any individual Development activity (including Non-Clinical or clinical studies) that is then-ongoing as of the effective date of termination; (ii) any non-cancelable costs associated with any individual Development activity that has been incurred by Cell Genesys or payable by Takeda for any individual Development activity that is then-ongoing as of the effective date of termination or terminated as of such date by Cell Genesys (provided that Cell Genesys shall use Diligent Efforts to minimize such costs as practicable); and (iii) to the extent any such individual Development activity cannot reasonably be terminated early, the conduct and completion of any individual Development activity (including Non-Clinical or clinical studies) that is scheduled to commence within a ninety (90) day period following Takeda's delivery of a notice of termination under this Agreement; in each case of (i), (ii) and (iii) as and to the extent such Development activity is described in the then-current Shared Territory Development Plan and ROW Territory Development Plan, including without limitation any VITAL Study. Cell Genesys shall have the right in its reasonable discretion to determine whether to commence, continue or terminate any of the activities described in this subsection (c) taking into account Diligent Efforts, and Takeda shall not fail to commence or terminate any Development activity described above in this Section 13.5(c) prior to the effective date of termination unless the Parties mutually agree to do so in good faith taking into consideration the exercise of Diligent Efforts; provided, that in no event shall Takeda be responsible for expenses in connection with such activities [for a period of time that exceeds the earlier of (x) two (2) years after the effective date of termination, or (y) the date on which Cell Genesys enters into an agreement with a Third Party to support, in whole or in part, the development or commercialization of the Product.]

**(d) Wind-Down.** The JDC shall coordinate the wind-down of Takeda's efforts under this Agreement or with respect to the terminated countries.

**(e) Regulatory Materials; Data.** To the extent permitted by applicable Laws, Takeda shall transfer and assign to Cell Genesys all Regulatory Materials, Regulatory Approvals, and related data relating to Products throughout the Licensed Territory or in the terminated countries, as applicable, as and to the extent owned or Controlled by Takeda.

**(f) Takeda License.**

(i) Except as provided in Section 13.5(f)(ii) below and to the extent a license to Takeda intellectual property is necessary or useful for the continued Development,

Manufacture, Commercialization or Distribution as conducted or contemplated to be conducted by Takeda as of the effective date of such termination, Takeda hereby grants to Cell Genesys, effective only in the event of such termination, (1) an exclusive, royalty-free license, with the right to grant multiple tiers of sublicenses, under the Takeda Patents, the Product Marks, and the Takeda Marks (excluding house marks), and (2) a non-exclusive, royalty-free license under the Takeda Know-How; in each case of (1) and (2) to develop, make, have made, use, sell, offer for sale, have sold, import and otherwise Commercialize the Products in the Licensed Territory or terminated countries, as applicable, which licenses shall be effective as of the date of such termination.

**(ii)** If Cell Genesys terminates this Agreement following the First Commercial Sale in any country of the Licensed Territory pursuant to Section 13.3, then ,to the extent a license to Takeda intellectual property is necessary or useful for the continued Development, Manufacture, Commercialization or Distribution as conducted or contemplated to be conducted by Takeda as of the effective date of such termination, Takeda shall negotiate in good faith with Cell Genesys the terms of (1) an exclusive, royalty-bearing license, with the right to grant multiple tiers of sublicenses, under the Takeda Patents, the Product Marks, and the Takeda Marks (excluding house marks), and (2) a non-exclusive, royalty-bearing license under the Takeda Know-How; in each case of (1) and (2) to develop, make, have made, use, sell, offer for sale, have sold, import and otherwise Commercialize the Products in the Licensed Territory or terminated countries, as applicable, which licenses shall be effective as of the date of such termination. The license agreement(s) shall be negotiated in good faith by the Parties and shall contain commercially reasonable financial and other terms commonly found in license agreements for similar products for similar uses and consistent with the criteria set forth in Diligent Efforts. If the Parties do not agree upon the terms of the license described in this Section 13.5(f)(ii) within ninety (90) days after initiating negotiations, then either Party may submit the matter to binding mediation as described in Section 14.5.

**(g) Transition Assistance**. For [up to two (2) years] following the effective date of such termination, Takeda shall provide such assistance, at no cost to Cell Genesys, as may be reasonably necessary or useful for Cell Genesys to commence or continue Developing, Manufacturing, Distributing or Commercializing Products in the Licensed Territory or the terminated countries, as applicable, to the extent Takeda is then performing or having performed such activities, including without limitation transferring or amending as appropriate, upon request of Cell Genesys, any agreements or arrangements with Third Party vendors to Develop, Manufacture, Distribute or Commercialize Products in the Licensed Territory or terminated countries, as applicable. To the extent that any such contract between Takeda and a Third Party is not assignable to Cell Genesys, then Takeda shall reasonably cooperate with Cell Genesys to arrange to continue to and provide such services from such entity or so long as may be reasonably necessary to transition such services, but in no event for more than [two (2) years] following the effective date of such termination. Takeda and Cell Genesys each shall exercise Diligent Efforts to complete any and all of such transition activities as soon as practicable.

**(h) Termination of Licenses**. For clarity, upon any termination of this Agreement by Takeda under Section 13.2(a), (b), or (c), or by Cell Genesys under Section 13.3, the licenses granted to Takeda under this Agreement for such terminated country(ies) shall terminate.

**(i) Partial Termination**. In the event of a termination by Takeda under Section 13.2(a), (b), or (c) for a particular country, such country shall be deemed excluded from the definition of Licensed Territory.

**13.6 Effect of Termination for Cell Genesys**. If Takeda has the right to terminate this Agreement pursuant to Section 13.3 and elects not to exercise such right, then the following shall apply (in addition to any other rights and obligations under Section 13.3 or otherwise under this Agreement with respect to such termination):

**(a) Legal Remedies**. Cell Genesys shall continue to be liable to Takeda for any uncured material breach, and Takeda shall be entitled to pursue all legal and equitable remedies arising from such material breach that are available to it. Following a final, non-appealable judgment pursuant to Section 14.3 (unless Cell Genesys in writing does not dispute Takeda's determination of Cell Genesys' material breach), of Cell Genesys' material breach of this Agreement, Takeda may elect, in lieu of receiving a payment of such damages from Cell Genesys, to offset Takeda's future payment obligations to Cell Genesys under this Agreement by the amount of damages determined and awarded to Takeda pursuant to Section 14.3 (or agreed to in writing by the Parties pursuant to Section 14.5(b)).

**(b) Committee Representation; Decision-Making**. If Cell Genesys' material breach of this Agreement remains uncured, then, upon the expiration of the cure period provided in Section 13.3, Takeda may also elect to require Cell Genesys to withdraw from the Committees established pursuant to Article 3, and in such event, Cell Genesys shall no longer have the right to participate in the activities of, and decision-making by, the Committees as provided in Articles 3 and 14.

**13.7 Rights in Bankruptcy**. All rights and licenses granted under or pursuant to this Agreement by Cell Genesys are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that Takeda, as the licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against Cell Genesys under the U.S. Bankruptcy Code, Takeda shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in Takeda's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon Takeda's written request therefor, unless Cell Genesys elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a), following the rejection of this Agreement by Cell Genesys upon written request therefor by Takeda.

**13.8 Survival**. The following provisions shall survive any expiration or termination of this Agreement for the period of time specified in the applicable section or, if no time is specified, indefinitely: Articles 1, 8 (solely with respect to payments that are due as of the effective date of such expiration or termination, or that become due in connection with such expiration or termination), 11, 12, 14, and 15, and Sections 4.3(d), 4.6, 5.7(d), 5.9, 8.8, 8.9, 9.1, 9.2, 9.3, 10.3, 10.4, 13.4, 13.5, 13.6, and 13.8. Termination or expiration of this Agreement for

any reason shall not release a Party from any liability or obligation that already has accrued prior to such expiration or termination, nor affect the survival of any provision hereto to the extent it is expressly stated to survive such termination.

## ARTICLE 14

## DISPUTE RESOLUTION

**14.1 Disputes**. The Parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to either Party's rights and/or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article 14 to resolve any controversy or claim arising out of, relating to or in connection with any provision of this Agreement, if and when a dispute arises under this Agreement.

**14.2 Referred from Committee.**

**(a) General**. Except as provided in Section 14.3(b), with respect to disputes arising from a Committee pursuant to the terms of Article 3, either Party may, by written notice to the other Party, have such dispute referred to each Party's Designated Executive for attempted resolution by good faith negotiations within thirty (30) days after such notice is received, or shorter if necessary to ensure patient safety or compliance with applicable Laws. If the Designated Executives are not able to resolve such dispute within such thirty (30) day period, then if such dispute does not relate to a matter described in Section 14.2(b), either Party may at any time thereafter pursue any legal, equitable or other remedy available to it in accordance with this Article 14.

**(b) Specific Decision-Making Rights**. Except as provided in Section 14.3(b), if the Designated Executives of the Parties are not able to resolve a dispute within the thirty (30) day period described above, and the matter is related to one of the areas listed below, then each of Cell Genesys and Takeda shall have the unilateral right to settle such matter as provided below.

**(i) Cell Genesys Decisions**. The Designated Executive of Cell Genesys shall have the right to make the final decision with respect to matters involving: (1) Development activities (other than with respect to regulatory matters) for the VITAL-1 Study or the Currently Ongoing Studies, and (2) the Manufacture of Product (including matters related to CMC, process development, vendor selection, or scale up); provided that in each case Takeda shall not have the right, without the prior written consent of Cell Genesys, to increase or decrease any Cell Genesys financial commitment set forth in this Agreement, a JSC-approved Shared Territory Development Plan or a JSC-approved Commercialization Plan through the exercise of its decision making rights under subsection (ii) below.

**(ii) Takeda Decisions**. The Designated Executives of Takeda shall have the right to make the final decision with respect to matters involving: (1) the VITAL-2 Study or any Additional Studies (provided that Takeda shall not materially increase Cell Genesys' obligations under any existing study or allocate any Additional Study to Cell Genesys

without Cell Genesys' prior written consent not to be unreasonably withheld, conditioned or delayed), (2) regulatory matters for the Product in the Licensed Territory under applicable Laws, (3) all Development activities to the extent not described in Section 14.2(b)(i), (4) Commercialization of the Product in the Licensed Territory, and (5) the selection of any additional Product under Section 4.8.

**14.3 Arising Between the Parties.**

**(a) General Matters.** Except as provided in Section 14.3(b) and except in connection with the matters described in Sections 8.2, 8.10, 13.5(f) and 14.2, with respect to all other disputes arising between the Parties and not from a Committee, including, without limitation, any alleged failure to perform, or breach of, this Agreement, or any issue relating to the interpretation or application of this Agreement, if the Parties are unable to resolve such dispute within thirty (30) days after such dispute is first identified by either Party in writing to the other, the Parties shall refer such dispute to the Designated Executive for each Party for attempted resolution by good faith negotiations within thirty (30) days after such notice is received. With respect to any dispute regarding an alleged material breach of this Agreement and termination under Section 13.3, if such dispute is not resolved by such Designated Executives within such period, then either Party may submit such dispute to mediation in accordance with Section 14.5. With respect to any other dispute that is not resolved by such Designated Executives within such period, either Party may at any time thereafter pursue any legal, equitable or other remedy available to it in accordance with this Article 14 and such dispute shall be submitted to a court of competent jurisdiction in the State of New York, United States of America. Each Party hereby consents to venue and personal jurisdiction in, and agrees to service of process issued or authorized by, such court.

**(b) Safety Matters.** In the event that the Parties cannot agree to one opinion with respect to an individual adverse event or other matter affecting the health, safety or welfare of a patient, then, the Parties shall convene the relevant Committee to discuss and seek resolution of such matter as expeditiously as possible to ensure patient safety and compliance with applicable Laws. In connection with such discussions, the Parties may convene any joint working groups or outside consultants and/or experts in the subject matter of the disagreement to assist the Parties to reach one opinion. If such discussions do not result in one opinion between the Parties in a reasonably timely fashion, then the most conservative opinion shall prevail.

**14.4 Injunctive Relief.** Nothing herein may prevent either Party from seeking a preliminary injunction or temporary restraint order in order to prevent any Confidential Information from being disclosed without appropriate authorization under this Agreement.

**14.5 Mediation.**

**(a) Binding; Certain Provisions.** Any dispute, claim or controversy arising under Sections 8.2, 8.10 or 13.5(f) shall be submitted to JAMS (or other mutually agreed applicable entity) for binding mediation or similar procedure to render a binding decision (as the Parties may agree). The mediator shall confer with the Parties to design procedures to conclude the mediation, including, if necessary, rendering a binding decision, within no more than sixty (60) days after initiation. Except for an action to obtain equitable relief, as provided in Section

14.5(c), neither Party may commence a civil action with respect to the matters submitted to mediation. The outcome of the mediation or, if necessary, the decision of the mediator shall be (i) in writing, stating the reasons for such decision; (ii) based solely on the terms and conditions of this Agreement, as interpreted, if applicable, in accordance with the laws of the State of New York; and (iii) final and binding upon the Parties hereto; and (iv) enforceable in any court of competent jurisdiction.

**(b) Non-binding; Material Breach.** Any dispute, claim or controversy regarding any proposed termination of this Agreement for material breach under Section 13.3 may be submitted by either Party, pursuant to Section 14.3(a), to JAMS for non-binding mediation. If such matter is not resolved within forty-five (45) days after initiation of mediation, then either Party may thereafter pursue any legal, equitable or other remedy available to it in accordance with Section 14.3(a). The mediator shall confer with the Parties to design procedures to conclude the mediation within no more than forty-five (45) days after initiation. Except for an action to obtain equitable relief, as provided in Section 14.5(c), neither Party may commence a civil action with respect to the matters submitted to mediation until at least forty-five (45) days after initiation of mediation. Mediation may continue after the commencement of a civil action, if the Parties mutually agree.

**(c) Procedure.** Either Party may commence mediation by providing to JAMS and the other Party a written request for mediation, setting forth the subject of the dispute and the relief requested. The Parties shall promptly confer in an effort to select a mediator from the JAMS panel of neutrals by mutual agreement. In the absence of such an agreement within ten (10) days of initiation of the mediation, the mediator shall be selected by JAMS. The Parties covenant that they will participate in the mediation in good faith, and that they will share equally in its costs. All offers, promises, conduct and statements, whether oral or written, made in the course of the mediation by any of the Parties, their agents, employees, experts and attorneys, and by the mediator and any JAMS employees, are confidential, privileged and inadmissible for any purpose, including impeachment, in any litigation or other proceeding involving the parties, provided that evidence that is otherwise admissible or discoverable shall not be rendered inadmissible or non-discoverable as a result of its use in the mediation. Either Party may seek equitable relief prior to the mediation to preserve the status quo pending the completion of that process. The provisions of this Section 14.5 may be enforced by any court of competent jurisdiction, and the Party seeking enforcement shall be entitled to an award of all costs, fees and expenses, including attorneys' fees, to be paid by the Party against whom enforcement is ordered. Either Party's failure to perform any obligation under this Agreement due to a pending good faith mediation proceeding or request to commence mediation shall not be deemed to be a material breach of this Agreement.

## ARTICLE 15

## MISCELLANEOUS

**15.1 Entire Agreement; Amendment.** This Agreement, including the Exhibits hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises,

agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior and contemporaneous agreements and understandings between the Parties with respect to the subject matter hereof; provided, that the Confidential Disclosure Agreement between the Parties dated January 17, 2007 shall continue in full force and effect in accordance with its terms. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

**15.2 Force Majeure**. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the control of the Parties, including without limitation, an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, and failure of plant or machinery (provided that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances). Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a force majeure affecting such Party. If a force majeure persists for more than ninety (90) days, then the Parties will discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such force majeure.

**15.3 Notices**. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 15.3, and shall be deemed to have been given for all purposes (a) when received, if hand-delivered or sent by confirmed facsimile or a reputable courier service, or (b) five (5) business days after mailing, if mailed by first class certified or registered airmail, postage prepaid, return receipt requested.

| | |
|---|---|
| If to Cell Genesys: | Cell Genesys, Inc.<br>500 Forbes Boulevard<br>South San Francisco, CA 94080<br>Attn: Senior Vice President, Corporate Development<br>Fax: (650) 266-2920 |
| With a copy to: | Cooley Godward Kronish LLP<br>Five Palo Alto Square<br>3000 El Camino Real<br>Palo Alto, CA 94306 |

Attn: Barbara A. Kosacz, Esq., Kenneth J. Krisko, Esq.

If to Takeda:

Takeda Pharmaceutical Company Ltd.
1-1, Doshomachi 4-Chome, Chuo-ku
Osaka 540-8645
Japan
Attn: General Manager, Global Licensing & Business Development Department
Fax: (+81) 6-6204-2328

With a copy to:

Takeda Pharmaceutical Company Limited
1-1, Doshomachi 4-Chome, Chuo-ku
Osaka 540-8645
Japan
Attn: General Manager, Legal Department
Fax: (+81) 6-6204-2055

And a copy to:

Takeda Pharmaceuticals North America, Inc.
One Takeda Parkway
Deerfield, Illinois 60015
U.S.A.
Attn: Alliance Manager
Fax: (224) 554-7881

**15.4 No Strict Construction; Headings**. This Agreement has been prepared jointly and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section. Except where the context otherwise requires, the use of any gender shall be applicable to all genders, and the word "or" is used in the inclusive sense (and/or). The term "including" as used herein means including, without limiting the generality of any description preceding such term.

**15.5 Assignment**. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that a Party may make such an assignment without the other Party's consent to Affiliates or to a successor to substantially all of the business of such Party to which this Agreement relates, whether in a merger, sale of stock, sale of assets or other transaction. Any successor or assignee of rights and/or obligations permitted hereunder shall, in writing to the other Party, expressly assume performance of such rights and/or obligations. The Cell Genesys Technology, in the case of Cell Genesys as assignor or transferor, or the Takeda Technology, in the case of Takeda as assignor or transferor, shall exclude any Patents and Information (a) Controlled by any permitted assignee or transferee prior to the effective date of such assignment or transfer of this Agreement to such assignee or transferee and (b) not developed in connection with any Product. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or

attempted assignment by either Party in violation of the terms of this Section 15.5 shall be null, void and of no legal effect.

**15.6 Performance by Affiliates**. Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

**15.7 Further Actions**. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

**15.8 Severability**. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

**15.9 No Waiver**. Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

**15.10 Independent Contractors**. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

**15.11 English Language; Governing Law**. This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof shall be governed by and construed under the laws of the State of New York, without giving effect to any choice of law principles that would require the application of the laws of a different state.

**15.12 Counterparts**. This Agreement may be executed in one (1) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement shall be binding upon the delivery by each Party of an executed signature page to the other Party, which may include by facsimile transmission.

**15.13 Change of Control**.

**(a) Definition.** For purposes of this Section 15.13, "Change of Control" of a Party shall occur if (i) any person or entity not an Affiliate of such Party acquires directly or indirectly the beneficial ownership of any voting security of a Party, or if the percentage ownership of such person or entity in the voting securities of a Party is increased through stock redemption, cancellation or other recapitalization, and immediately after such acquisition or increase such person or entity is, directly or indirectly, the beneficial owner of voting securities representing fifty percent (50%) or more of the total voting power of all of the then-outstanding voting securities of such Party; (ii) the consummation of a merger, consolidation, recapitalization, or reorganization of such Party, other than any such transaction which would result in stockholders or equity holders of such Party or an Affiliate of such Party immediately prior to such transaction owning at least fifty percent (50%) of the outstanding securities of the surviving entity in such transaction immediately following such transaction; or (iii) the stockholders or equity holders of a Party shall approve a plan of complete liquidation of the Party or an agreement for the sale or disposition by the Party of all or a substantial portion of the Party's assets, other than to an Affiliate.

**(b) Consequences.** Takeda shall have the right, exercisable within sixty days after the consummation of a Change of Control of Cell Genesys, but only one (1) time during the Term, to either (i) revoke the Co-Promotion Option or (ii) if Cell Genesys has already exercised the Co-Promotion Option, to terminate Cell Genesys' Co-Promotion rights, as applicable, in either case upon sixty (60) days prior written notice to Cell Genesys or its acquiror.

**[Signature Page Follows]**

**IN WITNESS WHEREOF**, the Parties have executed this Agreement in duplicate originals by their duly authorized officers as of the Effective Date.

**TAKEDA PHARMACEUTICAL COMPANY LIMITED**

By: _____

Name: Yasuchika Hasegawa

Title: President

**CELL GENESYS, INC**

By: _____

Name: Stephen A. Sherwin, MD

Title: Chairman and CEO

## EXHIBIT A
### PRODUCT DESCRIPTION

[The CG1940/CG8711 prostate cancer immunotherapy product consists of two lethally irradiated, allogeneic prostate adenocarcinoma cells that secrete human granulocyte-macrophage colony stimulating factor (GM-CSF). CG1940 (Galgenprostucel-L) and CG8711 (Litgenprostucel-L), the two components of CG1940/CG8711, are manufactured, packaged and inoculated separately, but administered together in the clinic. CG1940 and CG8711 were derived from human prostate adenocarcinoma cell lines, PC-3 and LNCaP respectively, by transduction ex vivo with a replication-defective, recombinant adeno-associated viral vector containing the human genomic (hgGM-CSF) gene under the transcriptional control of a heterologous viral promoter (rAAV-MD2-hgGM-CSF). The cells are presently formulated for intradermal injection in a cryoprotectant consisting of human serum albumin (HSA), hydroxyethyl starch (HES) and dimethyl-sulfoxide (DMSO) in Dulbecco's phosphate buffered saline (DPBS).]

# EXHIBIT A-1

# SPECIFICATIONS

| Product Release Specification | | |
|---|---|---|
| Doc. No.: **50012** | Item Name: **CG1940 (AAV Genomic GM-CSF Transduced PC-3) Final Product** | Page 1 of 3 |
| Item No.: **50012** | | |
| Cell Genesys Lot No.: | | |

| Description | |
|---|---|
| Product: | CG1940 consists of PC-3 cells (an established human prostate adenocarcinoma cell line) genetically modified by a recombinant adeno-associated virus (AAV) vector encoding the human genomic granulocyte macrophage colony stimulating factor (hGM-CSF) gene. CG1940 is produced in suspension culture, formulated in DPBS containing 2% HSA, 5% DMSO and 8% N-HES, filled at 4 to 6 x $10^7$ cells/mL and growth arrested by γ-irradiation. |
| Container/closure: | 1 mL glass vial (10043 or 10247) with rubber stopper (10040 or 10044), aluminum seal and green flip cap (10048) |
| Labeling: | Labeled for U.S. investigational use (10215 or 10217) |
| **Safety and Storage** | |
| Safety Precautions: | Biosafety level 1 |
| Storage Conditions: | Store at or below -135°C |
| Expiration period: | N/A – concurrent stability, protocol C-SSP-0036 |
| **Certificates of Analysis** | |
| Territory: | Document Number: |
| Composite | C-50012-A |
| USA | C-50012-B |
| Canada | C-50012-C |
| EU | C-50012-D |

| Product Release Specification | | |
|---|---|---|
| Doc. No.: **50012** | Item Name: **CG1940 (AAV Genomic GM-CSF Transduced PC-3) Final Product** | Page 2 of 3 |
| Item No.: **50012** | | |
| Cell Genesys Lot No.: | | |

| Analytical Criteria | | | |
|---|---|---|---|
| | **Test** | **Method**[1] | **Specification** |
| A. | Appearance A (frozen form) | Organoleptic C-TM-4093 | Opaque, colorless to beige |
| B. | Appearance B (liquid form) | Organoleptic C-TM-4093 | Transparent to translucent, colorless to beige |
| C. | Volume for injection | USP <1> volumetric C-TM-0008 | 1.0 - 1.2 mL |
| D. | Identity | HLA-B genetic analysis C-TM-0009 | PC-3 cells |
| E. | Viability | Trypan blue exclusion C-TM-0007 | ≥ 70.0% |
| F. | Cell concentration | Digital microscopy C-TM-0007 | 4.0 – 6.0 x $10^7$ cells/mL |
| G. | GM-CSF secretion | ELISA H-TM-0032 | 1200 - 4400 ng/$10^6$ cells |
| H. | GM-CSF potency | TF-1 cell culture activation H-TM-0014 | 50.0 – 200% of product reference |
| I. | Cell potency: expression of HER-2/neu, % positive | Flow Cytometry H-TM-0028 | ≥ 70% positive |
| J. | Cell potency: expression of HER-2/neu, ABC | Flow Cytometry H-TM-0028 | ≥ 20, 000 |
| K. | Cell potency: expression of CD13, % positive | Flow Cytometry H-TM-0029 | ≥ 70% positive |
| L. | Cell potency: expression of CD13, ABC | Flow Cytometry H-TM-0029 | ≥ 16,000 |
| M. | pH | Potentiometric C-TM-0011 | 6.4 – 7.0 |
| N. | Osmolality | Freezing point depression C-TM-0002 | 990.0 – 1700 mOsm/Kg $H_2O$ |
| O. | Conductivity | Electrochemical C-TM-0013 | 8.96 to 11.6 mS/cm |
| P. | Bulk sterility | USP/EP, direct inoculation Gibraltar Labs., Inc. GP456 | No microbial growth detected |



[1] Equivalent methods from approved, alternate laboratories may be substituted.

| Product Release Specification | | |
|---|---|---|
| Doc. No.: **50012** | Item Name: **CG1940 (AAV Genomic GM-CSF Transduced PC-3) Final Product** | Page 3 of 3 |
| Item No.: **50012** | | |
| Cell Genesys Lot No.: | | |

| Analytical Criteria | | | |
|---|---|---|---|
| | **Test** | **Method**[1] | **Specification** |
| Q. | Sterility | USP/EP, direct inoculation<br>Gibraltar Labs., Inc. GP456 | No microbial growth detected |
| R. | Mycoplasma | Points to Consider[2]/EP<br>Charles River Labs. GP-V611.10 | None detected |
| S. | Adventitious viruses (In-vitro) | In-vitro virus assay<br>BioReliance 003800 | None detected |
| T. | Endotoxin | USP/EP Bacterial Endotoxin by Gel-Clot LAL Method<br>C-TM-4065 | ≤ 12.0 EU/mL |
| U. | Adeno-associated virus (AAV) | Polymerase chain reaction (PCR)<br>BioReliance 105044FR | None detected |
| V. | Residual insulin | ELISA<br>H-TM-0048 | ≤ 1.0 µg/mL |



[1] Equivalent methods from approved, alternate laboratories may be substituted.
[2] Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals, CBER, 1993.

| Product Release Specification | | |
|---|---|---|
| Doc. No.: **50013** | Item Name: **CG8711(AAV Genomic GM-CSF, Transduced LNCaP) Final Product** | Page 1 of 3 |
| Item No.: **50013** | | |
| Cell Genesys Lot No.: | | |

| Description | |
|---|---|
| Product: | CG8711 consists of LNCaP cells (an established human prostate adenocarcinoma cell line) genetically modified by a recombinant adeno-associated virus (AAV) vector encoding the human genomic granulocyte macrophage colony stimulating factor (hGM-CSF) gene. CG8711 is produced in suspension culture, formulated in DPBS containing 2% HSA, 5% DMSO and 8% N-HES, filled at 4 to 6 X $10^7$ cells/mL and growth arrested by γ-irradiation. |
| Container/closure: | 1 mL glass vial (10043 or 10247) with rubber stopper (10040 or 10044), aluminum seal and yellow flip cap (10047) |
| Labeling: | Labeled for U.S. investigational use (10216 or 10218) |
| **Safety and Storage** | |
| Safety Precautions: | Biosafety level 1 |
| Storage Conditions: | Store at or below -135°C |
| Expiration period: | N/A – concurrent stability, protocol C-SSP-0035 |
| **Certificates of Analysis** | |
| Territory: | Document Number: |
| Composite | C-50013-A |
| USA | C-50013-B |
| Canada | C-50013-C |
| EU | C-50013-D |

| Product Release Specification | | |
|---|---|---|
| Doc. No.: **50013** | Item Name: **CG8711(AAV Genomic GM-CSF, Transduced LNCaP) Final Product** | Page 2 of 3 |
| Item No.: **50013** | | |
| Cell Genesys Lot No.: | | |

| Analytical Criteria | | | |
|---|---|---|---|
| | **Test** | **Method**[1] | **Specification** |
| A. | Appearance A (frozen form) | Organoleptic<br>C-TM-4093 | Opaque, colorless to beige |
| B. | Appearance B (liquid form) | Organoleptic<br>C-TM-4093 | Transparent to translucent, colorless to beige |
| C. | Volume for injection | USP <1> volumetric<br>C-TM-0008 | 1.0 – 1.2 mL |
| D. | Identity | HLA-B genetic analysis<br>C-TM-0009 | LNCaP cells |
| E. | Viability | Trypan blue exclusion<br>C-TM-0007 | ≥ 70.0% |
| F. | Cell concentration | Digital microscopy<br>C-TM-0007 | 4.0 – 6.0 x $10^7$ cells/mL |
| G. | GM-CSF secretion | ELISA<br>H-TM-0032 | 600.0 - 2800<br>ng/$10^6$ cells |
| H. | GM-CSF potency | TF-1 proliferation<br>H-TM-0018 | 50.0 – 200% of product reference |
| I. | Cell potency: expression of HER-2/neu, % positive | Flow Cytometry<br>H-TM-0028 | ≥ 70% positive |
| J. | Cell potency: expression of HER-2/neu, ABC | Flow Cytometry<br>H-TM-0028 | ≥ 37,000 |
| K. | Cell potency: expression of PSMA, % positive | Flow Cytometry<br>H-TM-0026 | ≥ 70% positive |
| L. | pH | Potentiometric<br>C-TM-0011 | 6.4 – 7.0 |
| M. | Osmolality | Freezing point depression<br>C-TM-0002 | 1000 – 1700 mOsm/Kg $H_2O$ |
| N. | Conductivity | Electrochemical<br>C-TM-0013 | 7.83 – 11.5 mS/cm |
| O. | Bulk sterility | USP/EP, direct inoculation<br>Gibraltar Labs., Inc. GP456 | No microbial growth detected |



[1] Equivalent methods from approved, alternate laboratories may be substituted.

| Product Release Specification | | |
|---|---|---|
| Doc. No.: **50013** | Item Name: **CG8711(AAV Genomic GM-CSF, Transduced LNCaP) Final Product** | Page 3 of 3 |
| Item No.: **50013** | | |
| Cell Genesys Lot No.: | | |

| Analytical Criteria | | | |
|---|---|---|---|
| | **Test** | **Method[1]** | **Specification** |
| P. | Sterility | USP/EP, direct inoculation<br>Gibraltar Labs., Inc. GP456 | No microbial growth detected |
| Q. | Mycoplasma | Points to Consider[2]/EP<br>Charles River Labs. GP-V611.10 | None detected |
| R. | Adventitious viruses (In-vitro) | In-vitro virus assay<br>BioReliance 003800 | None detected |
| S. | Endotoxin | USP/EP Bacterial Endotoxin by Gel-Clot LAL Method<br>C-TM-4065 | ≤ 12.0 EU/mL |
| T. | Adeno-associated virus (AAV) | Polymerase chain reaction (PCR)<br>BioReliance 105044FR | None detected |
| U. | Residual BSA | ELISA<br>C-TM-0010 | ≤ 12 µg/mL |
| V. | Residual trypsin | ELISA<br>H-TM-0015 | ≤ 1.0 µg/mL |
| W. | Residual human DNase I | ELISA<br>H-TM-0017 | ≤ 5.0 µg/mL |
| X. | Residual insulin | ELISA<br>H-TM-0048 | ≤ 1.0 µg/mL |



[1] Equivalent methods from approved, alternate laboratories may be substituted.
[2] Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals, CBER, 1993.

# EXHIBIT B-1
## CELL GENESYS PATENTS

| Invention Title | Case No. | Application No. | Patent No. | Country | File Date | Issue Date |
|---|---|---|---|---|---|---|
| [Method for Increasing Tumor Cell Immunogenicity Using Heat Shock Protein | CELL102/2 | 11/975236 | | United States of America | 17-Oct-2007 | |
| Cytokine-Expressing Cellular Vaccines for Treatment of Prostate Cancer | CELL131/0 | US05/032357 | | Canada | 09-Sep-2005 | |
| | CELL131/0 | 10/937658 | | United States of America | 10-Sep-2004 | |
| | CELL131/0 | 200580038526 | | China | 09-Sep-2005 | |
| | CELL131/0 | 5796370.4 | | European Patent Convention | 09-Sep-2005 | |
| | CELL131/0 | US05/032357 | | Patent Cooperation Treaty | 09-Sep-2005 | |
| | CELL131/0 | 2007-531416 | | Japan | 08-Mar-2007 | |
| Directly Injectable Formulations Which Provide Enhanced Cryoprotection of Allogeneic GVAX Cell Products | CELL137/0 | 2510503 | | Canada | 27-May-2005 | |
| | CELL 137/0 | 3800054.3 | | European Patent Convention | 28-Jun-2005 | |
| | CELL 137/0 | 2004-563893 | | Japan | 22-Dec-2003 | |
| | CELL137/0 | 10/323664 | 7176022 | United States of America | 20-Dec-2002 | 13-Feb-2007 |
| | CELL 137/0 | US03/40822 | | Patent Cooperation Treaty | 22-Dec-2003 | |
| | CELL137/0 | 10/323664 | 7176022 | United States of America | 20-Dec-2002 | 13-Feb-2007 |
| | CELL137/1 | 11/484,954 | | United States of America | 12-Jul-2006 | |
| Cytokine-Expressing Cellular Vaccine Combinations | CELL145/0 | 10/404662 | | United States of America | 02-Apr-2003 | |
| | CELL145/1 | 10/807449 | | United States of America | 24-Mar-2004 | |
| | CELL145/1 | 2519563 | | Canada | 24-Mar-2004 | |
| | CELL145/1 | 4759735.6 | | European Patent Convention | 18-Oct-2005 | |
| | CELL145/1 | US04/008846 | | Patent Cooperation Treaty | 24-Mar-2004 | |
| | CELL145/1 | 2006-507483 | | Japan | 03-Sep-2005 | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Novel Cancer-Associated Antigens and Methods of Their Identification and Use *(Cell Genesys' interest in such co-owned Patents)* | CELL92/1 | 2349217 | | Canada | 03-Nov-1999 | |
| | CELL92/1 | 13409/00 | 767842 | Australia | 03-Nov-1999 | 11/27/2003 |
| | CELL92/1 | US99/25936 | | Patent Cooperation Treaty | 03-Nov-1999 | |
| | CELL92/2 | 09/610891 | 7217421 | United States of America | 06-Jul-2000 | 15-May-2007 |
| | CELL92/3 | 11/274856 | 7226606 | United States of America | 16-Nov-2005 | 05-Jun-2007 |
| | CELL92/4 | 11/799854 | | United States of America | 02-May-2007 | |
| | CELL92/5 | 11/894663 | | United States of America | 20-Aug-2007 | |
| | CELL92/1 | 2000-580006 | | Japan | 03-Nov-1999 | |
| Cytokine-Expressing Cancer Immunotherapy Combinations | CELL169/1 | 11/728,660 | | United States of America | 27-Mar-2007 | |
| | CELL169/1 | US07/007897 | | Patent Cooperation Treaty | 28-Mar-2007 | ] |

**SUB-LICENSED**

| Invention Title | Case No. | Application No. | Patent No. | Country | File Date | Issue Date |
|---|---|---|---|---|---|---|
| [Regulation of Systemic Immune Responses Utilizing Cytokines and Antigens (*sublicensed from MIT and/or The Johns Hopkins University)* | WHI105/1 | 2120503 | 2120503 | Canada | 05-Oct-1992 | 04-Apr-2006 |
| | WHI105/3 | 551730 | 5637483 | United States of America | 23-Jun-1994 | 10-Jun-1997 |
| | WHI105/4 | 08/486854 | 5904920 | United States of America | 07-Jun-1995 | 18-May-1999 |
| | WHI105/1 | 27776/92 | 677165 | Australia | 05-Oct-1992 | 17-Aug-1997 |
| | WHI105/1D | 2002123.4 | 1216710 | Belgium | 05-Oct-1992 | 05-Apr-2006 |
| | WHI105/1 | 92921896.4 | 607309 | France | 05-Oct-1992 | 08-Jan-2003 |
| | WHI105/1D | 2002123.4 | 1216710 | France | 05-Oct-1992 | 05-Apr-2006 |
| | WHI105/1 | 92921896.4 | 607309 | Federal Republic of Germany | 05-Oct-1992 | 01-Aug-2003 |
| | WHI105/1D | 2002123.4 | 69233614 | Federal Republic of Germany | 05-Oct-1992 | 18-May-2006 |
| | WHI105/1 | 92921896.4 | 607309 | Italy | 05-Oct-1992 | 08-Jan-2003 |
| | WHI105/1 | 507110/93 | 3580371 | Japan | 05-Oct-1992 | 30-Jul-2004 |
| | WHI105/1 | US92/08455 | | Patent Cooperation Treaty | 05-Oct-1992 | |
| | WHI105/1D | 2002123.4 | 1216710 | Liechentstein | 05-Oct-1992 | 05-Apr-2006 |
| | WHI105/1D | 2002123.4 | 1216710 | Monaco | 05-Oct-1992 | 05-Apr-2006 |
| | WHI105/1D | 2002123.4 | 1216710 | Netherlands | 05-Oct-1992 | 05-Apr-2006 |
| | WHI105/4 | 96/4850 | 96/4850 | South Africa | 07-Jun-1996 | 26-Mar-1997 |
| | WHI105/4 | US96/08422 | | Patent Cooperation Treaty | 03-Jun-1996 | |
| | WHI105/1 | 92921896.4 | 607309 | Spain | 05-Oct-1992 | 01-Aug-2003 |
| | WHI105/1D | 2002123.4 | 1216710 | Switzerland | 05-Oct-1992 | 05-Apr-2006 |
| | WHI105/1D | 2002123.4 | 1216710 | United Kingdom | 05-Oct-1992 | 05-Apr-2006 |
| Transfer vectors and microorganisms containing human cytomegalovirus immediate-early promoter-regulatory DNA sequence *(sublicensed from the University of Iowa)* | Uiowa | 07/582,130 | 5,168,062 | United States of America | 9/10/1990 | 12/1/1992 |
| | | 07/900,056 | 5,385,839 | United States of America | 6/17/1992 | 1/31/1995] |

# EXHIBIT B-2
## TAKEDA PATENTS

[NONE ]

# EXHIBIT B-3
## UPSTREAM AGREEMENTS

| Other Party(ies) | Title of Agreement | Effective Date |
|---|---|---|
| [University of Iowa Research Foundation | License Agreement | November 30, 1996 |
| Massachusetts Institute of Technology<br><br>Whitehead Institute for Biomedical Research | Amended and Restated Exclusive Patent License Agreement | December 17, 1998 |
| The Johns Hopkins University | License Agreement | June 15, 2000 |
| The Johns Hopkins University | License Agreement | March 12,2001] |

# EXHIBIT C
## SHARED TERRITORY DEVELOPMENT PLAN

[

**2008**

**CLINICAL**
- VITAL-1
  - Freeze database for: (1) all patient data supporting first approximately 200 deaths, and (2) all demographic, initial treatment and initial safety data for all patients.
- VITAL-2
  - Accrue approximately 500 patients
- Currently Ongoing Studies
  - Complete treatment of patients in G-0016 (combination with anti-CTLA4 antibody)
  - Initiate investigator-sponsored I-0057 trial

**MANUFACTURING**
- Complete all final Product quality control release assays.
- Complete manufacture of three 500L lots to support comparability testing
- Finalize design specifications for packaging line
- Supply Product to support Product nonclinical and clinical development

**2009**

**CLINICAL**
- VITAL-1
  - Implement plans to enable database lock within 3 months of receipt of the 400th death
- VITAL-2
  - Complete accrual per protocol
  - Freeze database for: (1) all patient data supporting the specified number of deaths in the protocol required for interim analysis, and (2) all demographic, initial treatment data and initial safety data for all patients
  - Enable planned interim analysis within approximately 6 weeks of receipt of the specified number of deaths required per protocol in the clinical database
- Currently Ongoing Studies
  - Complete follow up of patients in G-0016 (combination with anti-CTLA4 antibody)
  - Complete accrual and treatment in investigator-sponsored I-0057 trial (combination with neoadjuvant docetaxel)

**MANUFACTURING**
- Submit IND amendment for 500L production process to FDA, including results of comparability testing and lot release assays from three 500L lots
- Complete process pre-validation activities and manufacture one validation/conformance lot of each cell line at 500L scale
- Supply Product to support Product nonclinical and clinical development

**MAA**
- Complete significant portions of

**2010**

**CLINICAL**
- VITAL-1
  - Complete final study report to enable MAA filing
- VITAL-2
  - Implement plans to enable database lock within 3 months of receipt of the last death required per protocol
  - Complete study report for MAA if both trials are required for MAA filing (based on accrual timelines)
- Currently Ongoing Studies
  - Complete follow up of patients in I-0057 trial (combination with neoadjuvant docetaxel)

**MANUFACTURING**
- Complete procurement, installation and validation of all downstream process equipment (e.g., controlled rate freezer, packaging line, material handling equipment)
- Complete manufacturing of remaining 2 validation/ conformance lots of each cell line at 500L scale
- Be ready for pre-approval inspection (PAI) for Shared Territory and ROW Territory by MAA filing
- Prepare for first commercial shipment by MAA approval

**MAA**
- File first MAA in window of 2Q-4Q

the CMC and nonclinical
modules required for MAA

**Cell Genesys, Inc.**

**VITAL Studies**

**Out of Pocket & Clinical Supply Cost Summary**

**(in millions $)**

| | Budget | | | | | Forecasts | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Out of Pocket Costs** | **Q1 FY08** | **Q2 FY08** | **Q3 FY08** | **Q4 FY08** | **2008** | **2009** | **2010** | **2011** | **Total** |
| **Clinical (CRO, Consultants, Lab Services, Site Payments)** | | | | | | | | | |
| VITAL-1 | 1.7 | 1.7 | 1.2 | 1.2 | 5.9 | 3.4 | 1.6 | 0.6 | 11.5 |
| VITAL-2 | 2.8 | 2.6 | 2.7 | 2.8 | 10.9 | 8.4 | 2.5 | 1.1 | 22.9 |
| Total Clinical | 4.5 | 4.3 | 4.0 | 4.0 | 16.8 | 11.8 | 4.2 | 1.7 | 34.4 |
| **Shipping & Distribution** | 0.7 | 0.7 | 0.7 | 0.7 | 2.9 | 2.9 | 0.7 | - | 6.4 |
| **Taxotere** | 1.9 | - | 1.9 | - | 3.9 | 2.0 | - | - | 5.9 |
| **Regulatory (Consultants)** | 0.2 | 0.2 | 0.2 | 0.2 | 0.8 | 0.8 | 0.7 | - | 2.3 |
| **Medical Affairs (Consultants)** | 0.4 | 0.3 | 0.4 | 0.4 | 1.4 | 1.5 | 1.5 | - | 4.3 |
| **Total Out of Pocket Costs** | 7.7 | 5.6 | 7.2 | 5.3 | 25.8 | 19.0 | 6.9 | 1.7 | 53.4 |
| **Clinical Supply Costs** | | | | | | | | | |
| **Direct Labor Costs** | 0.6 | 0.6 | 0.6 | 0.6 | 2.4 | 1.3 | - | - | 3.6 |
| **Direct Raw Materials & Supply Costs** | 0.3 | 0.01 | 0.3 | 0.2 | 0.8 | 0.2 | - | - | 0.9 |
| **Direct External Quality & In Process Control Costs** | 0.1 | 0.1 | 0.1 | 0.1 | 0.5 | 0.2 | - | - | 0.7 |
| **Related Facility & Quality Assurance/Quality Control Costs** | 1.4 | 1.5 | 1.3 | 1.3 | 5.5 | 2.7 | - | - | 8.2 |
| **Warehousing** | 0.1 | 0.1 | 0.1 | 0.1 | 0.2 | 0.2 | | | 0.5 |
| **Total Clinical Supply Costs** | 2.5 | 2.3 | 2.4 | 2.2 | 9.3 | 4.6 | - | - | 13.9 |
| **Total Out of Pocket & Clinical Supply Cost** | **10.2** | **7.9** | **9.6** | **7.4** | **35.1** | **23.6** | **6.9** | **1.7** | **67.3** |

## EXHIBIT D
## CO-PROMOTION TERMS

**1. General.** Cell Genesys shall perform a portion of the aggregate Detailing efforts to oncologists (the "**Co-Promotion Target Audience**"), subject to the limits described in Section 6.12(b), which level shall be specified in the notice of exercise of the Co-Promotion Option by Cell Genesys ("**Election Percentage**") in accordance with the terms of the Agreement, such aggregate Detailing effort to be specified in the Commercialization Plan. Based on the Election Percentage, the Co-Promotion Agreement shall be structured to reflect the following:

- The allocation of Details for the Co-Promotion Target Audience will take into consideration prescribing levels, geographic territory, centers of excellence and other considerations as the Parties may agree.

- In accordance with the scope of the Commercialization Plan, Takeda may increase or decrease the overall sales force effort for the Product to the Co-Promotion Target Audience. If Takeda increases such sales force efforts, Cell Genesys has the right, but not the obligation, to increase its total sales force efforts within thirty (30) days of receipt of notice from Takeda in order to maintain its Election Percentage. If Takeda decreases such sales force efforts, Cell Genesys shall have the right, at its option, to make a corresponding decrease to its Detail efforts to maintain its Election Percentage or to maintain its then-current level of sales efforts without regard to the applicable cap on its Election Percentage; provided, however, Cell Genesys shall not have this right if Takeda's decrease is as a result of Cell Genesys' exercise of the Co-Promotion Option during the Post-Launch Window.

- Cell Genesys shall employ its expertise, best professional judgment and, where applicable, its working relationships with the Co-Promotion Target Audience to ensure that the sales force used for the promotion of the Product (the "**Sales Force**") Details the Products in a manner aimed at maximum appropriate prescription generation.

- Each Party shall implement and maintain an appropriate incentive plan for the sale of the Product for its sales force that provides an incentive on an interval to be specified in the Co-Promotion Agreement and is weighted at a level commensurate with the Product Detail position for the Product within the total number of products handled by such sales force.

- Cell Genesys will provide the Detailing activities under this Agreement in accordance with the most recent Commercialization Plan provided by Takeda.

**2. Cell Genesys' Ability to Terminate.** Cell Genesys shall not terminate co-promotion activities until [after the first anniversary of the launch of the Product in the United States if such rights were exercised in the Pre-Launch Window, and at any time thereafter Cell Genesys may terminate co-promotion activities upon six (6) months prior written notice to Takeda].

**3. Promotional Materials and Samples.** Takeda will provide to Cell Genesys, at Takeda's expense, reasonable quantities of promotional materials and product samples and/or sample vouchers for the Product to support Cell Genesys' co-promotion activities (it being understood that the Co-Promotion Agreement also will describe the manner in which the Products will be presented and described to the medical community in any promotional materials as permitted by applicable law and the labeling for the Product). Cell Genesys shall not and shall ensure that the Sales Force does not make any changes in the promotional materials. Cell Genesys shall be responsible for the costs of returning or destroying any unused product samples and/or sample vouchers and promotional materials for the Product, subject to Takeda's sample accountability policies.

**4. Training and Related Cell Genesys Sales Force Issues.**

Takeda shall provide initial training to Cell Genesys' sales managers and trainers (*i.e.*, "train-the-trainer") [at Takeda's expense]. Thereafter, Cell Genesys and Takeda will each be responsible for conducting training of their own sales forces. Takeda will be responsible for designing training materials. Takeda will ship training materials to Cell Genesys as reasonably required for Cell Genesys' ongoing training needs [at Cell Genesys' expense].

- At the request of a Party, such Party's trainers may participate in the other Party's training programs specific to Products.

- Cell Genesys shall be responsible (at its own expense) for establishing training (other than the training provided by Takeda), supervising and maintaining the Sales Force.

- Cell Genesys will be permitted to participate in any continuing medical education programs, speaker meetings, advisory board meetings, grants, charitable contributions and/or promotional events (including, but not limited to displays and exhibit booths) related to the Product.

- At Cell Genesys' reasonable request, Takeda shall advise Cell Genesys on sales force strategy and promotional activities in assisting the development of Cell Genesys' co-promotion efforts.

**5. Termination; Shortfalls.**

- The term of the Co-Promotion Agreement shall commence on the effective date of the Co-Promotion Agreement and shall expire, if not terminated earlier, upon the discontinuation of sales of the Products in all countries within the Shared Territory.

- The Co-Promotion Agreement shall contain other reasonable and appropriate termination rights.

- If in any calendar year either Party fails to perform at least X percent of the number of Details assigned to it pursuant to the Commercialization Plan, then, as further to be detailed in the Co-Promotion Agreement, the other Party will have the right to [make up

the shortfall in Details in the following calendar year and the non-performing Party will reimburse the other Party for any such Details performed by it at a premium rate to be set forth in the Co-Promotion Agreement]. The Parties will negotiate in good faith the foregoing X percentage in the Co-Promotion Agreement taking into consideration the principles contained in the definition of Diligent Efforts.

- If either Party fails to perform at least Y percent of the Details allocated to it in the Commercialization Plan in any calendar year or at least Z percent of the Details allocated to it in the Commercialization Plan in each of two consecutive calendar quarters, then the other Party, in addition to the rights provided above, shall have the right to, in the case of Cell Genesys, [suspend Takeda's rights to Commercialize the Product (and perform the Details to be allocated to Takeda)], and in the case of Takeda, [suspend Cell Genesys' Co-Promotion rights, in each case for no more than three (3) years]. The Parties will negotiate in good faith the foregoing Y and Z percentages in the Co-Promotion Agreement taking into consideration the principles contained in the definition of Diligent Efforts.

**6. Detail and Sample Reporting**

- Each Party will maintain complete and accurate records of the Details it performs.
- The Parties will agree on a report format and frequency of reporting and sampling procedures if applicable.

**7. Medical Inquires**

- The Parties will agree on procedures for handling any medical inquires from health care professionals or others and any requests for medical information about the Product.

**8. Adverse Events**

- The Parties will establish a process for communicating and reporting any adverse events and complaints relating to the Product.

## EXHIBIT E
### SUPPLY AGREEMENT TERMS

This Exhibit E describes the basic scope and principles to be included in the Supply Agreement, which will govern supply of both clinical (following receipt of the first Regulatory Approval) and commercial quantities of the Product (as described in Section 1.69(a)) or each Additional Product as Cell Genesys may Manufacture pursuant to the terms of Article 7 of the Agreement (for clarity, both such products are referred to as a Product in this Exhibit subject to the terms of Article 7).

**Scope**

1) Each Party shall appoint appropriate representatives from CGI and Takeda to negotiate the Supply Agreement.
2) The Supply Agreement shall describe and define the procedures, terms and conditions for forecasting, manufacture, quality control, delivery terms, price, payment and appropriate other activities relating to the supply of the Product in the Field and in the Licensed Territory and shall contain such other terms and conditions customarily contained in agreements of this type.

**Price/ Payment**

1) The purchase price for commercial supply shall be equal to: (a) Cell Genesys' Fully Burdened Manufacturing Cost (as defined below). The parties note that to date [Cell Genesys has limited experience with the commercial scale manufacturing process for the Product and related pricing matters, however, it is understood that the per vial costs are affected by the total volume of product produced in the plant in a given period]. In no event shall the purchase price for commercial supply in the Licensed Territory exceed the following percentages of Net Sales calculated using the price for the Shared Territory on a per unit basis: (i) [30%] for the first [12 months] following First Commercial Sale of Product; (ii) [25%] for the subsequent [12 month] period; and (iii) [20%] thereafter.

2) The purchase price described above shall include a discount mechanism based on purchase volume. The price to be applied to any individual purchase order will be determined based on [the trailing twelve month] purchased volume up to and including that order.

3) The Supply Agreement will include a mechanism for periodic review of Fully Burdened Manufacturing Cost. Cell Genesys will make Diligent Efforts to reduce the Fully Burdened Manufacturing Costs. The Parties shall include an incentive to reduce such costs in the Supply Agreement.

4) As used herein, "Fully Burdened Manufacturing Cost" means [the consolidated fully burdened cost] incurred by Cell Genesys in the Manufacture of Product calculated in accordance with GAAP, including the following: [(i) direct and indirect cost of any

materials; (ii) direct labor costs (including benefits); (iii) factory overhead (fixed and variable); (iv) operating costs of facilities and equipment (including idle plant capacity); (v) a charge for depreciation and repairs and maintenance costs of facilities and equipment; (vi) quality and in-process control costs; and (vii) charges for spoilage and scrap], in each case as such costs are determined in accordance with Cell Genesys' accounting practices applied on a consistent basis. Notwithstanding the foregoing, cost of manufacture shall not include [any manufacturing variances attributable to other products or any profit related to inter-company transfer pricing]. To the extent that Manufacturing of Products for commercial sale, or any component thereof, is performed for Cell Genesys by a Third Party, amounts paid by Cell Genesys to such Third Party directly for such Manufacture will be added, without mark up, to the aggregate amount of the foregoing items; provided, however, any payment for [process development] made to such Third Party as a result of such Third Party performing [development work on a manufacturing process] for Cell Genesys will be excluded from any calculation of Fully-Burdened Manufacturing Cost.

5) Takeda will have the right to audit Cell Genesys' Fully Burdened Manufacturing Costs in accordance with reasonable and customary audit provisions as to be agreed in the Supply Agreement.

**Transfer of Analytical Methods (QA)**

1) In order to implement the technical transfer of quality tests for the Product, Cell Genesys will provide to Takeda or its designee all information and materials required to perform quality testing on the Product. If Takeda requests, Cell Genesys will provide reasonable support for the technical transfer of analytical methods. The costs for such transfer and services shall be borne by [Cell Genesys].

**Second Source**

1) The Supply Agreement will contain the detailed procedures for implementing the Second Source Plan in accordance with Section 7.4 of the Agreement.

2) Takeda shall pay all costs, other than Cell Genesys' Internal FTE Costs, associated with qualifying, initiating and maintaining the second source provider as to be detailed in the Second Source Plan.

**Other Terms**

1) Takeda shall issue purchase orders for Product for delivery [6 months] prior to delivery date.
2) Takeda will provide rolling forecasts of its requirements for Additional Studies (anticipated between [12-18] months), at least the first [three (3)] months of which

will be binding. The parties will determine the frequency of the forecasting in the Supply Agreement. Outside the binding period the forecasts may be adjusted by up to X% and be subsequently binding on Cell Genesys. Adjustments above + X% will be subject to a reasonable efforts requirement on Cell Genesys to provide. The parties will determine the foregoing percentages in the Supply Agreement.

3) The Supply Agreement will contain mutually agreed information sharing and planning procedures with respect to the Product.

4) The Supply Agreement will contain change control procedures for the Specifications and other related matters. Change requests will be made pursuant to a written change request form agreed by both parties. The change request will also document any changes to estimated timelines and costs. The parties must mutually agree to any changes to the Specifications. Takeda will bear the cost of any approved changes requested by it or in connection with any change to comply with regulatory requirements for the ROW Territory.

5) Payment terms are net 30 days from receipt of invoice (invoice will not be issued prior to shipment).

6) Cell Genesys will procure and retain all capital equipment to meet obligations under the Supply Agreement.

7) [Takeda will reimburse Cell Genesys] for capital equipment expenditures through amortization of such costs over the expected economic life of such equipment (as reasonably determined by Cell Genesys in consultation with Takeda) to be included in the commercial supply price.

8) Takeda will have the right to audit Cell Genesys' costs in accordance with mutually acceptable audit procedures.

Delivery

1) Delivery requirements, location and Incoterms shall be defined in the Supply Agreement.

Manufacture and Quality Control

1) Product shall be manufactured in compliance with cGMP, as defined by Regulatory Authorities within the Licensed Territory, and the Regulatory Approval.
2) The Supply Agreement shall define terms and conditions for audit by each party of cGMP activities within the other's operation.
3) The Supply Agreement shall define a procedure for notification of each party in the event of a product complaint from the field or product recall.
4) The Supply Agreement shall define a procedure for resolution of any disputes regarding product quality.
5) The Supply Agreement shall define safety and waste handling procedures relating to the Product and its Manufacture.
6) Some or all of these items may be included in the Quality Agreement.

Quality Agreement

1) The parties will work in good faith to complete a quality agreement on a mutually agreed time frame prior to First Commercial Sale of the Product, or as soon as practicable following the Effective Date if the Parties determine a quality agreement is necessary with respect to clinical supply of Product.

Inability to Supply

1) In the event that Cell Genesys is unable to supply Product [meeting the Specifications in quantities and a time period to be established in the Supply Agreement] based upon Takeda's binding purchase orders, Takeda shall have the right to [purchase the shortfall quantities (subject to any reasonable minimum supply requirements of the alternate supplier)] from one or more additional suppliers of the Product during the period of Cell Genesys' inability to supply. In connection with any such failure to supply, upon Takeda's request, Cell Genesys will be obligated to promptly complete a technology transfer in accordance with procedures to be established in the Supply Agreement and the Collaboration Agreement. Takeda will use Diligent Efforts to resume purchasing Product from Cell Genesys within a reasonable period of time. Cell Genesys shall use Diligent Efforts to avoid being unable to supply Product meeting the Specifications in quantities sufficient to fulfill Takeda's binding purchase orders.

Product Warranty

1) Cell Genesys will provide Product warranties no less stringent than those contained in Section 7.2(e).

Limitation of Liabilities/Limited Remedy

1) Neither Takeda nor Cell Genesys shall be liable to the other for any special, indirect, incidental or consequential damages (including, but not limited to lost profits or revenues) arising from the agreement under any theory of law.

Safety Stock

1) The Parties shall maintain the safety stock for the Product in accordance with Section 7.4 of the Agreement.

Recalls

1) Recall costs will be (i) the responsibility of a Party, to the extent its negligence, breach of this Agreement or the Supply Agreement or other willful misconduct resulted in the recall, or (ii) shared equally if neither Party's negligence, breach of this Agreement or the Supply Agreement or other willful misconduct resulted in the recall.

## EXHIBIT F
### PRESS RELEASE

CELL GENESYS

Takeda

FOR IMMEDIATE RELEASE

**Cell Genesys and Takeda Announce Global Alliance for the Development and Commercialization of GVAX Immunotherapy for Prostate Cancer**

**SOUTH SAN FRANCISCO, Calif. and OSAKA, Japan,** March 31, 2008 (United States) and April 1, 2008 (Japan)—Cell Genesys, Inc. ("Cell Genesys", Nasdaq: CEGE) and Takeda Pharmaceutical Company Limited ("Takeda", TSE: 4502) today announced that the companies have formed a global alliance for the development and commercialization of GVAX immunotherapy for prostate cancer, Cell Genesys' lead product candidate currently in Phase 3 clinical development.

Under the agreement, in exchange for exclusive worldwide commercial rights to GVAX immunotherapy for prostate cancer, Takeda will pay Cell Genesys an upfront payment of $50 million and additional milestone payments totaling up to $270 million relating to regulatory approval and commercialization of GVAX immunotherapy for prostate cancer in the United States, European Union and Japan. Takeda will pay Cell Genesys tiered, double-digit royalties based on net sales of GVAX immunotherapy for prostate cancer in the United States and flat double-digit royalties based on net sales of the product in all other regions. From this point forward, Takeda will pay for all external development costs associated with the ongoing Phase 3 clinical development of GVAX immunotherapy for prostate cancer and will also pay for all additional development costs and all commercialization costs. Cell Genesys will maintain responsibility for the worldwide manufacture and supply of the product and will retain rights to co-promote GVAX immunotherapy for prostate cancer in the United States.

"We are very pleased to have entered into this agreement with Takeda for the development and commercialization of GVAX immunotherapy for prostate cancer and look forward to benefiting from Takeda's impressive record of success as a global pharmaceutical business and clear commitment to become a leader in the field of oncology," stated Stephen A. Sherwin, M.D., chairman and chief executive officer of Cell Genesys. "In particular, we are very glad to have the opportunity to work with the company that pioneered the global development and commercialization of the world's leading prostate cancer drug, Lupron®, and hope to build on that success with GVAX immunotherapy for prostate cancer, a potential new treatment option for men with this disease."

"We are excited to have added GVAX immunotherapy for prostate cancer to our growing oncology pipeline and are eager to do all that we can to ensure its commercial success in the United States and globally," said Yasuchika Hasegawa, president of Takeda. "Our extensive experience in the prostate cancer market, coupled with our global infrastructure of development and marketing makes us well-suited to work in partnership with Cell Genesys in the effort to make GVAX immunotherapy for prostate cancer a reality for patients in need."

GVAX immunotherapy for prostate cancer is currently being evaluated in two Phase 3 clinical trials, VITAL-1 and VITAL-2, in patients with advanced prostate cancer. The U.S. Food and Drug Administration has granted Cell Genesys Fast Track status for the GVAX prostate cancer program and both trials have completed Special Protocol Assessment agreements. In 2007, the VITAL-1 trial completed enrollment with 626 patients and in January 2008, Cell Genesys announced that the Independent Data Monitoring Committee (IDMC) had completed a pre-planned interim analysis for VITAL-1 and recommended that the study continue. The IDMC

provided no information to the company other than the recommendation to continue the trial. The company currently estimates that there will be sufficient events to trigger the final analysis for VITAL-1 in the second half of 2009. Patients are continuing to be enrolled in the VITAL-2 trial at approximately 100 clinical trial sites located in North America and Europe. Cell Genesys is targeting the completion of enrollment for VITAL-2 with approximately 600 patients in the first half of 2009 and expects that there will be sufficient events to trigger the pre-planned interim analysis in the same time frame.

**About GVAX Immunotherapy for Prostate Cancer**

Cell Genesys' GVAX cancer immunotherapies are whole-cell products that are designed to present the immune system with a broad spectrum of tumor antigens and stimulate an immune response against the patient's tumor. GVAX immunotherapy for prostate cancer is comprised of two prostate tumor cell lines that have been modified to secrete GM-CSF (granulocyte-macrophage colony stimulating factor), an immune stimulatory hormone that plays a key role in stimulating the body's immune response, and then irradiated for safety. GVAX for prostate cancer is being developed as a non patient-specific, "off-the-shelf" pharmaceutical product. The company is currently manufacturing the product in its bioreactor manufacturing facility in Hayward, California, a facility that is also capable of producing the product for commercialization.

**About Cell Genesys**

Cell Genesys is focused on the development and commercialization of novel biological therapies for patients with cancer. The company is currently pursuing two clinical stage product platforms – GVAX™ cancer immunotherapies and oncolytic virus therapies. Ongoing clinical trials include Phase 3 trials of GVAX immunotherapy for prostate cancer, Phase 2 trials of GVAX immunotherapies for pancreatic cancer and for leukemia, and a Phase 1 trial of CG0070 oncolytic virus therapy for bladder cancer. Cell Genesys continues to hold an equity interest in its former subsidiary, Ceregene, Inc., which is developing gene therapies for neurodegenerative disorders. Cell Genesys is headquartered in South San Francisco, CA and has its principal manufacturing operation in Hayward, CA. For additional information, please visit the company's website at www.cellgenesys.com.

**About Takeda**

Located in Osaka, Japan, Takeda (TSE:4502) is a research-based global company with its main focus on pharmaceuticals. As the largest pharmaceutical company in Japan and one of the global leaders of the industry, Takeda is committed to striving toward better health for individuals and progress in medicine by developing superior pharmaceutical products. Additional information about Takeda is available through its corporate website, www.takeda.com.

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*Forward-Looking Statement for Cell Genesys*

*Statements made herein about the company, other than statements of historical fact, including statements about the expectations regarding the agreement with Takeda, the company's progress, results, analysis, enrollment and timing of VITAL-1 and VITAL-2 and other clinical trials and preclinical programs and the nature of product pipelines are forward-looking statements and are subject to a number of uncertainties that could cause actual results to differ materially from the statements made, including risks associated with the success of clinical trials and research and development programs, regulatory requirements and the regulatory approval process for clinical trials, manufacture and commercialization of the company's products, competitive technologies and products, patents, the need for and reliance on partnerships with third parties and the risks inherent in partnership with third parties, and the need for additional financings. For information about these and other risks which may affect Cell Genesys, please see the company's reports on Form 10-Q, 10-K, and 8-K and other reports filed from time to time with the Securities and Exchange Commission. The company assumes no obligation to update the forward-looking information in this press release.*

*Forward-Looking Statement for Takeda*

*This press release contains forward-looking statements regarding the Company's plans, outlook, strategies and results for the future. All forward-looking statements are based on judgments derived from the information available to the Company at this time.*
*Certain risks and uncertainties could cause the Company's actual results to differ materially from any projections presented in this press release. These risks and uncertainties include, but are not limited to, the economic circumstances surrounding the Company's business; competitive pressure; relative laws and regulations; product development programs; and changes in exchange rates.*
*We assume no obligation to update or reverse any forward-looking statements or other information contained in this press release, whether as a result of new information, future events, or otherwise.*

# # #

# EXHIBIT G
## TRADEMARKS

### CG Marks

| Mark | Country | Class | App No. (& App Date) | Reg. No. (& Reg. Date) |
|---|---|---|---|---|
| CELL GENESYS | Canada | | 761844 (8/17/94) | TMA64861 (9/19/2005) |
| CELL GENESYS | USA | 5 | 76/232,409 (3/29/01) | 2604222 (8/6/02) |
| CELL GENESYS | USA | 42 | 74/120,794 (12/05/90) | 1772613 (5/18/93 |
| CELL DESIGN | USA | 1, 5, 42 | 74/322003 (10/8/92) | 2052995 (4/15/97) |
| CHANGING THE FUTURE OF ONCOLOGY | USA | 42 | 76/401235 (4/26/02) | 2780479 (11/4/03) |
| GVAX | USA | 42 | 77/096096 (2/1/07) | |

### Product Marks

| Mark | Country | Class | App No. (& App Date) | Reg. No. (& Reg. Date) |
|---|---|---|---|---|
| CIRZEDE | USA | 5 | 78/809427 (2/7/06) | ALLOWED (7/10/07) |
| CAPTEOS | USA | 5 | 78/809353 (2/7/06) | ALLOWED (7/10/07) |
| ENEDROS | USA | 5 | 78/809357 (2/7/06) | ALLOWED (7/10/07) |
| TROCAPSA | USA | 5 | 77/038568 (11/7/06) | PENDING |

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