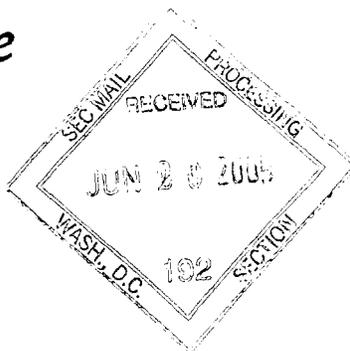


# Media Release

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SUPPL

Basel, 15 June 2005

## **FDA approves oral Xeloda for the adjuvant (after surgery) treatment of colon cancer**

**Colon cancer patients have access to a new effective and more convenient treatment**

Roche announced today that the U.S. Food and Drug Administration (FDA) has approved Xeloda (capecitabine), an innovative oral chemotherapy, for the adjuvant (post-surgery) treatment of colon cancer patients.

Adjuvant chemotherapy is the standard treatment approach for Dukes' C colon cancer (Stage III cancer that has spread to the lymph nodes), where chemotherapy is given after the tumour has been surgically removed. This approval will now give patients who have undergone complete resection of their primary tumour the option of an oral chemotherapy when treatment with fluoropyrimidine therapy alone is preferred. Xeloda as an oral fluoropyrimidine compares favourably with intravenous infusion requiring multiple hospital visits.

"Following European approval in March 2005 the FDA also supports Xeloda's new indication. This again confirms Roche's commitment to providing innovative solutions for patients, while providing medical resource cost savings for today's healthcare providers", said William M. Burns, CEO Division Roche Pharma. "For the first time colon cancer patients will have access to a unique treatment option that provides an effective oral therapy which is well-tolerated and can be taken at home."

The FDA's decision was based on the landmark X-ACT (Xeloda in Adjuvant Colon Cancer Therapy) trial. The trial successfully met its primary endpoint, showing Xeloda is non-inferior to 5-FU/LV for disease-free survival.<sup>1</sup>

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At this time, neither Xeloda nor combination chemotherapy has been shown to prolong overall survival; combination chemotherapy has demonstrated an improvement in disease free survival compared to 5-FU/LV.

On average, a patient only needed 8 hospital visits when treated with Xeloda compared to 30 visits if treated with i.v. 5-FU/LV<sup>2</sup>. This results in significant cost savings - an important advantage for doctors, nurses and pharmacists in today's healthcare environment.

Roche has a large ongoing study programme looking at Xeloda in combination with other chemotherapies and targeted therapies in breast and colon cancer.

"More than 145,000 Americans will be diagnosed with colon cancer this year, so it's important that the cancer community continually seeks to improve available treatment options," said Carolyn Aldige, President of the Cancer Research and Prevention Foundation. "We commend Roche's commitment, as evidenced by today's FDA approval, to bringing effective and more convenient options to patients with colon cancer."

#### About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As a supplier of innovative products and services for the early detection, prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is a world leader in diagnostics, the leading supplier of medicines for cancer and transplantation and a market leader in virology. In 2004 sales by the Pharmaceuticals Division totalled 21.7 billion Swiss francs, while the Diagnostics Division posted sales of 7.8 billion Swiss francs. Roche employs roughly 65,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. For further information: [www.roche.com](http://www.roche.com)

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#### Additional information:

- Presentation of the X-ACT trial: [www.asco.org/ac/1.1003\\_12-002511-00\\_18-0026-00\\_19-009534-00\\_21-00400.asp](http://www.asco.org/ac/1.1003_12-002511-00_18-0026-00_19-009534-00_21-00400.asp), "Capecitabine vs. bolus 5-FU/leucovorin as adjuvant therapy for colon cancer (the X-ACT study): positive efficacy results of a phase III trial"

- Colorectal cancer: [www.roche.com/pages/downloads/company/pdf/mbg010405c.pdf](http://www.roche.com/pages/downloads/company/pdf/mbg010405c.pdf)
- Xeloda in colorectal cancer:  
[www.roche.com/pages/downloads/company/pdf/mbg010405a.pdf](http://www.roche.com/pages/downloads/company/pdf/mbg010405a.pdf)
- Xeloda: [www.roche.com/pages/downloads/company/pdf/mbg010405r.pdf](http://www.roche.com/pages/downloads/company/pdf/mbg010405r.pdf)
- Roche in oncology: [www.roche.com/pages/downloads/company/pdf/mboncolov05e\\_b.pdf](http://www.roche.com/pages/downloads/company/pdf/mboncolov05e_b.pdf)
- Broadcast quality B-roll including doctor and patient interviews is available for download via [www.thenewsmarket.com](http://www.thenewsmarket.com)

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#### References:

1. Reddy, G. Efficacy of adjuvant capecitabine compared with bolus 5-Fluorouracil/Leucovorin regimen in Duke's C colon cancer: results from the X-ACT trial. *Clin Colorectal Cancer*, July 2004; 87-88.
2. McKendrick, J.J, Cassidy, J, et al. Capecitabine (x) is resource saving compared with i.v. bolus 5-FU/LV in adjuvant chemotherapy for Duke's C colon cancer patients: Medical resource utilization (MRU) data from large phase III trial (X-ACT). *Journ of Clin Oncol*, 2004 ASCO Annual Meeting Proceedings (Post Meeting Edition). Vol 22, No 14S (July supplement), 2004: 3578

#### Notes for Editors:

##### About Xeloda

Xeloda is indicated as a single agent for adjuvant treatment in patients with Duke's C colon cancer who have undergone complete resection of the primary tumor when treatment with fluoropyrimidine therapy alone is preferred. Xeloda was non-inferior to 5-fluorouracil and leucovorin (5-FU/LV) for disease-free survival (DFS). Although neither Xeloda nor combination therapy prolongs overall survival (OS), combination chemotherapy has been demonstrated to improve disease-free survival compared to 5-FU/LV. Physicians should consider these results when prescribing single-agent Xeloda in the adjuvant treatment of Duke's C colon cancer. Xeloda is covered by Medicare.

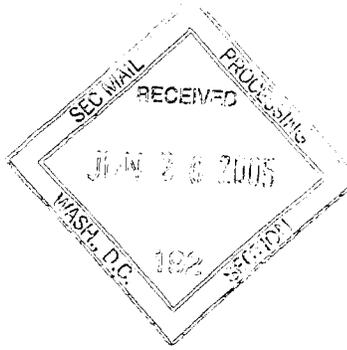
##### Xeloda Safety Information

A clinically important drug interaction between Xeloda and warfarin has been demonstrated; altered coagulation parameters and/or bleeding and death have been reported. Clinically significant increases in prothrombin time (PT) and INR have been observed within

days to months after starting Xeloda, and infrequently within one month of stopping Xeloda. For patients receiving both drugs concomitantly, frequent monitoring of INR or PT is recommended.

Age greater than 60 and a diagnosis of cancer independently predispose patients to an increased risk of coagulopathy. Xeloda is contraindicated in patients who have a known hypersensitivity to 5-fluorouracil, and in patients with known dihydropyrimidine dehydrogenase (DPD) deficiency. Xeloda is contraindicated in patients with severe renal impairment. For patients with moderate renal impairment, dose reduction is required. Xeloda can induce diarrhea, sometimes severe. Patients with severe diarrhea should be carefully monitored. Patients 80 and older receiving Xeloda monotherapy may experience a greater incidence of grade 3 or 4 adverse events. Xeloda may cause fetal harm when given to a pregnant woman. Women of childbearing potential should be advised to avoid becoming pregnant while receiving treatment with Xeloda. It is recommended that nursing be discontinued when using Xeloda. Men should use birth control when using Xeloda.

Common adverse events in the adjuvant setting were: diarrhea (Xeloda 47%, 5-FU/LV 65%), nausea (Xeloda 34%, 5-FU/LV 47%), stomatitis (Xeloda 22%, 5-FU/LV 60%), vomiting (Xeloda 15%, 5-FU/LV 21%), fatigue (Xeloda 16%, 5-FU/LV 16%) and hand-foot syndrome (Xeloda 60%, 5-FU/LV 9%). As with any cancer therapy, there is a risk of side effects, and these are usually manageable and reversible with dose modification or interruption. Visit <http://www.xeloda.com> or call Roche at 800-526-6367.



## Investor Update

Friday, June 17, 2005 8:47 AM

### Biologics Manufacturing Facility to be Purchased by Genentech from Biogen Idec

Dear Investor,

Please find attached the news release issued by Genentech and Biogen Idec concerning the purchase of Biogen Idec's biologics manufacturing facility by Genentech.

Please do not hesitate to contact us if you have further questions.

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### BIOLOGICS MANUFACTURING FACILITY TO BE PURCHASED BY GENENTECH FROM BIOGEN IDEC

CAMBRIDGE, Mass. And SOUTH SAN FRANCISCO, Calif. (June 16, 2005) - Biogen Idec (NASDAQ: BIIB) and Genentech, Inc. (NYSE: DNA) announced today an agreement for Genentech to purchase Biogen Idec's NIMO Oceanside, California biologics manufacturing facility. The approximately 430 employees currently at the facility are expected to be offered employment at Genentech or retained by Biogen Idec.

"This acquisition will position us to improve delivery of life-extending and life-improving therapies to patients with unmet medical needs. We expect the facility will play an important role in helping us deliver against our aggressive production plan," said Patrick Y. Yang, Ph.D., Genentech's senior vice president, Product Operations. "We view the Oceanside facility as a potentially unique and valuable asset, in terms of the manufacturing facilities, the added capacity and the addition of highly-skilled employees who will join our team."

The parties have signed a purchase and sale agreement. The transaction is subject to various closing conditions. If the conditions are met, the parties anticipate closing the sale as early as June 23, 2005. Under terms of the agreement, Genentech will pay Biogen Idec approximately \$408 million in cash for the 60-acre, 500,000 square-foot facility. The Oceanside plant, completed in December 2004, has 90,000 liters of bioreactor capacity. Genentech expects biologic manufacturing of Avastin(TM) (bevacizumab) at the plant to commence in 2006 with Food and Drug Administration (FDA) licensure anticipated in the first half of 2007. Of the approximately 430 employees currently working at the Oceanside facility, it is anticipated that approximately 330 will be offered employment by Genentech, and Genentech currently intends to hire approximately 200 additional employees at the facility by the end of 2006.

Biogen Idec expects to incur charges in the range of approximately \$50 to \$57 million, after income tax, in connection with the sale.

Following the closing of the transaction, Genentech will provide details of this transaction and an update on its overall manufacturing plans in a Webcast on or before its second quarter earnings announcement scheduled for July 11, 2005.

#### About Biogen Idec

Biogen Idec creates new standards of care in oncology, neurology and immunology. As a global leader in the development, manufacturing, and commercialization of novel therapies, Biogen Idec transforms scientific discoveries into advances in human healthcare. For product labeling, press releases and additional information about the company, please visit [www.biogenidec.com](http://www.biogenidec.com).

#### About Genentech

Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes biotherapeutics for significant unmet medical needs. A considerable number of the currently approved biotechnology products originated from or are based on Genentech science. Genentech manufactures and commercializes multiple biotechnology products directly in the United States and licenses several additional products to other companies. The company has headquarters in South San Francisco, California and is traded on the New York Stock Exchange under the symbol DNA. For additional information about the company, please visit [www.gene.com](http://www.gene.com).

This press release contains forward-looking statements by Biogen Idec regarding the sale of NIMO and related assets, the impact of the sale on the employees at NIMO and their future employment, and the amount and timing of charges Biogen Idec expects to incur in connection with the sale. These statements are based on the current expectations of Biogen Idec management. There are a number of risks and uncertainties that could cause actual results to differ materially, including that Biogen Idec and Genentech may be unable to satisfy all of the conditions to closing the sale, and that Biogen Idec may incur unexpected expenditures, costs and charges related to the sale. For more detailed information on the risks and uncertainties associated with Biogen Idec's business activities see the reports that Biogen Idec files with the SEC. Biogen Idec does not undertake any obligation to publicly update its forward-looking statements, whether as a result of new information, future events, or otherwise.

This press release contains forward-looking statements of Genentech regarding improved delivery of therapies, delivering on an aggressive production plan and timeframe for biologics manufacturing in 2006 and FDA licensure in 2007. Actual results could differ materially. Among other things, the timeframe for biologics manufacturing and FDA licensure could be affected by a number of factors, including product safety, efficacy or manufacturing issues, and FDA actions or delays or failure to receive FDA approval; delivering on an aggressive production plan could be impacted by actual demand for products exceeding internal forecasts, the inability to increase production output or to secure alternate sources of capacity or

filling issues; and delivery of therapies could be affected by all of the foregoing as well as competition, pricing, reimbursement, the ability to supply product, product withdrawals, new product approvals and launches, achieving sales revenue consistent with internal forecasts, unanticipated expenses such as litigation or legal settlement expenses, costs of sales and R&D expenses. Genentech disclaims, and does not undertake, any obligation to update or revise any forward-looking statements in this press release.

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## Investor Update

Friday, June 17, 2005 1:17 PM

### **PEGASYS Plus Ribavirin Significantly More Effective than Monotherapy in Landmark Japanese Clinical Trial** **61% Sustained Virologic Response In Japanese Patients with Difficult-to-Treat Hepatitis C**

Japanese hepatitis C patients treated with a combination of PEGASYS (peginterferon alfa-2a (40KD)) plus ribavirin have double the rate of response compared to patients treated with PEGASYS as monotherapy, according to results presented at the 41st Annual Conference of the Japan Society of Hepatology in Osaka (June 16-17, 2005). Results from a landmark phase III Japanese clinical trial show that 61% of treatment naïve genotype 1b patients in the combination therapy arm achieved a sustained virological response (SVR, which is indicative of a cure) compared with 26% of patients who received PEGASYS alone.

'This trial provides compelling evidence that PEGASYS in combination with ribavirin provides significant benefits for Japanese patients with hepatitis C' said *Ciro Caravaggio*, Life Cycle Leader for Hepatitis. 'The SVR achieved in these difficult-to-treat naïve patients with genotype 1b hepatitis C are the highest we have seen in Japanese phase III clinical trials.'

The key results of the study are:

- In patients who were treatment naïve, genotype 1b, a 61% SVR was achieved for those who received PEGASYS plus ribavirin. This is compared to an SVR of 26% for patients who received PEGASYS as monotherapy. The difference is statistically significant ( $P < 0.001$ )
- In patients who were pretreated with conventional interferon but did not respond or relapsed (so called 'nonresponders' or 'relapsers') the overall response rate was 54% with PEGASYS plus ribavirin
- Difficult to treat patients with an initially high viral load also responded well to the combination therapy with an SVR of 56% in the combination therapy group compared with 16% in the monotherapy group - a 3-fold increase in SVR

No additional safety considerations with combination therapy

Overall, the side effect profile was similar in both of the treatment groups and there was no difference in withdrawal rates. The most common side effects were influenza-like symptoms. Also, abnormal laboratory values such as neutropenia and thrombocytopenia, were similar in all patient groups. As expected, the rate of anemia was higher in patients who received ribavirin.

About the study design

This is the largest phase III clinical trial to examine the efficacy and safety profile of the combination of PEGASYS plus ribavirin in Japanese patients. The trial was conducted in 43 centers in Japan and enrolled 300 patients.

The trial consisted of two main treatment groups:

- Genotype 1b patients with no previous treatment
- In a randomized, placebo controlled, double blind trial design, a total of 201 naïve patients with Genotype 1b were assigned to receive PEGASYS 180ug once weekly plus daily ribavirin (600-1000mg, depending on body weight) or PEGASYS 180ug once weekly plus placebo

- Patients previously treated with conventional interferon therapy

In an open trial design, 100 patients who were previously treated with conventional interferon but did not respond to treatment (so called "Nonresponder") or patients who responded but then relapsed (so called "Relapser") were re-treated with PEGASYS 180ug once a week plus daily ribavirin (600-1,000 mg depending on body weight).

All patients were treated for 48 weeks and followed for an additional 24 weeks after stopping the study medication. The primary end point was the sustained virologic response (defined as the absence of detectable HCV RNA 24 weeks after stopping treatment).

#### About PEGASYS

PEGASYS is marketed in Japan by Chugai Pharmaceutical Co.Ltd. In Japan, PEGASYS was approved in October 2003 with the indication for monotherapy treatment of chronic hepatitis C and is marketed under the tradename of PEGASYS. PEGASYS, the market leader worldwide in hepatitis C therapy, provides significant benefit over conventional combination interferon therapy in hepatitis C patients of all genotypes. The benefits of PEGASYS are derived from its large 40 kilodalton (KD) branched-chain polyethylene glycol (PEG) construction, which allows for sustained drug levels over the course of a full week. PEGASYS also distributes more readily to the liver (the primary site of infection) than conventional interferon. PEGASYS is the only pegylated interferon available as a ready-to-administer solution. Each weekly subcutaneous injection contains 180mcg of pegylated interferon alfa-2a (40KD), which is the approved starting dose for all patients, regardless of body weight.

#### About Ribavirin

Ribavirin is currently being developed in Japan by Chugai Pharmaceutical Co Ltd. Outside Japan, this drug is used as an anti-virus therapy for treatment of various types of infectious diseases. The ribavirin used in this trial is a ribavirin tablet (overseas trade name: "COPEGUS") developed by Roche for use in combination with "PEGASYS" for the treatment of chronic hepatitis C.

#### About Hepatitis C

Hepatitis C is a potentially life threatening viral infection that can lead to liver inflammation, liver disease, cirrhosis or liver cancer. Transmitted primarily through infected blood, more than 170 million people world wide are infected making it more common than HIV virus.

#### About Genotype

Genotype is the classification of genes of the hepatitis C virus. The dominant genotypes in Japanese patients are 1b, 2a, and 2b. 1b in particular accounts for 70% of the total intractable chronic hepatitis C in Japan and is considered to be difficult to treat.

#### About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As a supplier of innovative products and services for the prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is a world leader in Diagnostics, the leading supplier of medicines for cancer and transplantation and a market leader in virology. In 2004, sales by the Pharmaceuticals Division totalled 21.7 billion Swiss francs, while the Diagnostics Division posted sales of 7.8 billion Swiss francs. Roche employs roughly 65,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. Additional information about the Roche Group is available on the Internet ([www.roche.com](http://www.roche.com)).

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