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Media Release

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Basel, 24 May 2006

Herceptin approved in Europe for early use in HER2-positive breast cancer

Life-extending drug offers new hope to women with aggressive form of breast cancer across Europe

Roche today announced that the European Commission has approved Herceptin (trastuzumab) for patients with early-stage HER2-positive breast cancer following surgery and standard chemotherapy. HER2-positive breast cancer, which affects approximately 20% to 30%[1] of women with breast cancer, demands special and immediate attention because the tumours are fast-growing and there is a higher likelihood of relapse.

The approval is based on impressive results from the international HERA (HERceptin Adjuvant) study which showed Herceptin following standard chemotherapy significantly reduces the risk of cancer coming back by 46% compared to chemotherapy alone.[2] Similarly remarkable benefits have also been seen in three other major global and US studies.[3]

"The remarkably quick manner in which Herceptin has received European approval in early-stage breast cancer is commendable" commented William M. Burns, CEO of Roche's Pharmaceuticals Division. "Herceptin has clearly demonstrated that it provides the best chance of long-term survival when used as early as possible in the course of the disease, and this decision is great news for patients and the medical community. We will now work with national authorities to ensure that this treatment is accessible to physicians and patients throughout Europe."

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Herceptin was previously approved in the EU for the treatment of metastatic (advanced) HER2-positive breast cancer, so this new approval allows women with all stages of this aggressive disease, including early-stage breast cancer, to access this life-extending treatment option.

The strength of results from four large trials with over 12,000 patients has influenced medical and regulatory organizations around the world to act urgently to ensure access to Herceptin for early-stage HER2-positive breast cancer patients. Herceptin was recently granted approval status in New

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Zealand and Australia, and several countries over the past year have developed clinical guidelines and committed funding to allow eligible patients faster access, prior to license.

In the US, Genentech filed a supplemental Biologic License Application (sBLA) for the use of Herceptin in early-stage HER2-positive breast cancer with the Food and Drug Administration (FDA) on February 15th, 2006. The application is based on data from the combined interim analysis of two large US trials,[4] and Genentech has received a priority review designation.

About the HERA study

HERA, conducted by the Roche and Breast International Group (BIG),[5] is one of the largest adjuvant studies ever carried out among breast cancer patients; enrolment to the trial began in December 2001, and nearly 5,100 HER2-positive patients were enrolled at 480 sites in 39 countries across the world. HERA is a randomised trial, which, following standard adjuvant systemic chemotherapy and radiotherapy (if applicable), evaluates observation versus Herceptin every three weeks for 12 months or 24 months in women with early-stage HER2-positive breast cancer. The HERA study allowed for the use of a wide range of chemotherapy regimens, and both lymph node-positive and lymph node-negative patients were eligible for entry into the trial.

According to the interim analysis, the primary efficacy endpoint was met, showing that in the 12-month arm, patients who received Herceptin had a statistically significant improvement in disease-free survival (the length of time after treatment during which no disease is found). At a median follow-up of one year, the secondary endpoint of overall survival had not reached statistical significance, but showed a clear trend towards an improvement in overall survival, which is to be confirmed as the data mature.

The interim analysis compared Herceptin versus observation and did not include a comparison of 12 months versus 24 months treatment duration. The trial will continue to assess this comparison and data will become available in due time as the study matures.

The HERA study has an external Independent Data Monitoring Committee (IDMC) that regularly reviews safety data. No safety concerns were raised by the IDMC, and the incidence of congestive heart failure was very low (0.5% in the Herceptin arms vs. 0% in the observation arm). Patients in this study will continue to be followed for any side effects.

About breast cancer and Herceptin

Eight to nine percent of women will develop breast cancer during their lifetime, making it one of the most common types of cancer in women.[6] Each year more than one million new cases of breast cancer are diagnosed worldwide, with a death rate of nearly 400,000 people per year.

In HER2-positive breast cancer, increased quantities of the HER2 protein are present on the surface of the tumour cells. This is known as 'HER2 positivity.' High levels of HER2 are present in a particularly aggressive form of the disease which responds poorly to chemotherapy. Research shows that HER2-positivity affects approximately 20-30% of women with breast cancer.

Herceptin is a humanised antibody, designed to target and block the function of HER2, a protein produced by a specific gene with cancer-causing potential. In addition to its efficacy in the early-stage breast cancer setting, Herceptin also has demonstrated improved survival in the advanced (metastatic) setting, where its addition to chemotherapy allows patients to live up to one-third longer than chemotherapy alone.[7]

Herceptin received approval in the European Union in 2000 for use in patients with metastatic breast cancer, whose tumours overexpress the HER2 protein. In addition to being indicated for use in combination with docetaxel as a first-line therapy in HER2-positive patients who have not received chemotherapy for their metastatic (advanced) disease, it is also indicated as a first-line therapy in combination with paclitaxel where anthracyclines are unsuitable, and as a single agent in third-line therapy. Herceptin is marketed in the United States by Genentech, in Japan by Chugai and internationally by Roche. Since 1998, Herceptin has been used to treat over 230,000 HER2-positive breast cancer patients worldwide.

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 2005 sales by the Pharmaceuticals Division totalled 27.3 billion Swiss francs, and the Diagnostics Division posted sales of 8.2 billion Swiss francs. Roche employs roughly 70,000 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

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Additional information:

- About Genentech: www.gene.com
- Roche in Oncology: www.roche.com/pages/downloads/company/pdf/mboncology05e_b.pdf
- Roche Health Kiosk on cancer: www.health-kiosk.ch/start_krebs
- Video clips (in broadcast standard, free of charge): www.thenewsmarket.com

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References:

[1] Harries M, Smith I. The development and clinical use of trastuzumab (Herceptin). Endocr Relat Cancer 9: 75-85, 2002.
[2] Piccart-Gebhart M, Procter M, Leyland-Jones B, et al. A Randomized Trial of Trastuzumab Following Adjuvant Chemotherapy in Women with HER2 Positive Breast Cancer. New England Journal of Medicine 353:16 2005.
[3] NCCTG N9831 (US), NSABP B-31 (US), BCIRG 006 (international)
[4] Romond, E., Perez, E. et al. Trastuzumab plus Adjuvant Chemotherapy for Operable HER2 Positive Breast Cancer. New England Journal of Medicine 353:16 2005.
[5] Collaborative partners for the HERA study include: Roche, BIG and its affiliated collaborative groups, plus non-affiliated collaborative groups, and independent sites.
[6] World Health Organization, 2000.
[7] Extra JM, Cognetti F, Maraninchi D et al. Long-term survival demonstrated with trastuzumab plus docetaxel: 24-month data from a randomised trial (M77001) in HER2-positive metastatic breast cancer. Abstract #555, American Society for Clinical Oncology (ASCO) Annual Meeting 2005.

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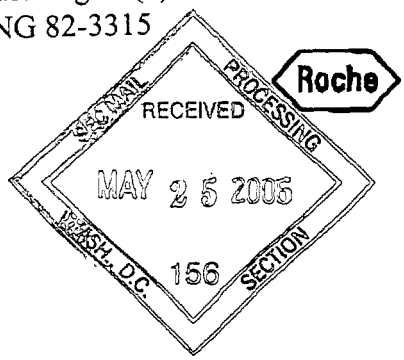

Basel, 23 May 2006

Recruitment to resume in AVANT international phase III trial in post-surgical adjuvant colon cancer

Temporary suspension of recruitment to be lifted following analysis of safety data

Roche announced today their intention to resume patient recruitment into the AVANT trial, a study of different combination chemotherapies, including two Roche medicines, Xeloda and Avastin, for post-surgical adjuvant treatment of colon cancer.

The decision to lift the temporary hold on recruitment was taken following the recommendation by the AVANT independent Data Safety Monitoring Board (DSMB). The DSMB concluded that the current safety profile and the death rates from all causes in AVANT were consistent with those seen in other adjuvant colon cancer trials. Thus, no concerns were raised about continuing recruitment in AVANT.
Patient recruitment will therefore resume upon clearance by the relevant Independent Review Boards and Health Authorities.

Professor Aimery de Gramont, Principal Investigator for AVANT stated: "We are very pleased to resume recruitment. The AVANT trial provides a unique opportunity to investigate whether combining an anti-angiogenic agent with standard chemotherapy in the adjuvant colon cancer setting will enhance patient outcomes. We are confident that the AVANT study results will open new avenues of treatment for patients with colon cancer."

Ed Holdener, Head of Global Development at Roche said "We welcome this recommendation from the DSMB. Patient safety is of utmost importance to us and it is essential that safety data are carefully monitored, particularly in the adjuvant treatment setting where patients have an additional chance of being cured of their cancer by post-surgical therapy."

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About the safety review of the AVANT study

Since the AVANT trial began in December 2004, approximately two thirds of the target number of 3,450 patients have been enrolled. On February 14, 2006, patient recruitment was temporarily halted to enable the DSMB to undertake a review of 60-day safety data. Patients who had already enrolled into the AVANT trial prior to the recruitment suspension have continued treatment according to the study protocol. This review was initiated for two reasons: a potential safety signal observed in one of the three study arms and the fast recruitment in the AVANT trial, which could impede adequate and timely intervention. The data review undertaken by the DSMB with a cut-off date of April 25, 2006 revealed that the all cause mortality excluding deaths due to recurrent colon cancer, in the AVANT trial for FOLFOX-4 (Arm A) was 0.8% (6 cases), for FOLFOX-4 + Avastin (Arm B) 0.5% (4 cases) and for XELOX + Avastin (Arm C) 1.05% (8 cases). These rates are consistent with those reported in other adjuvant studies in colon cancer. In order to gain further insights into the potential occurrence of cardiac events and sudden deaths, the AVANT study protocol will be amended to include a Cardiac Monitoring Plan (CMP*) .

About AVANT

The AVANT trial is a 3-arm global study (308 centers from 33 countries) randomizing high-risk stage II and stage III patients with colon cancer to FOLFOX-4 (infused/bolus 5-FU/LV + oxaliplatin), FOLFOX-4 plus Avastin, or XELOX (capecitabine + oxaliplatin) plus Avastin (arms A, B and C respectively). The objectives of AVANT are to assess whether adding Avastin to the chemotherapy regimens FOLFOX-4 or XELOX can prolong disease-free survival (i.e. whether it can reduce the chance of the cancer recurring) in patients who had no evidence of disease after curative surgery and to determine the safety profile of Avastin when used in combination with FOLFOX-4 or XELOX in the adjuvant setting.

About Avastin

Avastin is the first treatment that inhibits angiogenesis – the growth of a network of blood vessels that supply nutrients and oxygen to cancerous tissues. Avastin targets a naturally occurring protein called VEGF (Vascular Endothelial Growth Factor), a key mediator of angiogenesis, thus choking off the blood supply that is essential for the growth of the tumour and its spread throughout the body (metastasis).

Avastin is the first and only anti-angiogenic agent to have demonstrated improved overall and/or progression-free survival in the three major types of cancer leading to death: colorectal cancer, non-small cell lung cancer and breast cancer. In Europe, Avastin was approved early 2005 for first-line treatment of patients with metastatic carcinoma of the colon or rectum in combination with the

chemotherapy regimens of intravenous 5-fluorouracil/folinic acid or intravenous 5-fluorouracil/folinic acid/irinotecan. Avastin received approval by the US Food and Drug Administration (FDA) in February 2004. In addition, filing occurred in the US on April 10, 2006, for use of Avastin in previously untreated advanced non-squamous, non-small cell lung cancer and in Japan on April 21, 2006 for use of Avastin in patients with advanced or recurrent colorectal cancer

Avastin has a well-established safety profile. In Genentech-sponsored studies, the most serious adverse events associated with Avastin were gastrointestinal perforation, wound healing complications, hemorrhage, arterial thromboembolic events, hypertensive crisis, nephrotic syndrome and congestive heart failure. The most common Grade 3-4 adverse events (occurring in greater than two percent of patients in the Avastin arm, compared to the control group) were asthenia, pain, hypertension, diarrhea and leukopenia.

Roche and Genentech are pursuing a comprehensive clinical program investigating the use of Avastin in multiple tumor types (including colorectal, breast, lung, pancreatic cancer, ovarian cancer, renal cell carcinoma, prostate and others) and different settings (advanced and adjuvant ie post-operation). The total development program is expected to include over 25,000 patients worldwide.

About Xeloda

Xeloda is licensed in more than 90 countries worldwide including the EU, USA, Japan, Australia and Canada and has been shown to be effective, safe, simple and convenient oral chemotherapy treating over 1 million patients to date.

Roche received marketing authorisation for Xeloda as a first-line monotherapy (by itself) in the treatment of metastatic colorectal cancer (colorectal cancer that has spread to other parts of the body) in most countries (including the EU and USA) in 2001. Xeloda has also been approved by the European Medicines Agency (EMEA) and U.S. Food and Drug Administration (FDA) for adjuvant (post-surgery) treatment of colon cancer in March and June 2005, respectively.

Xeloda is licensed in combination with Taxotere (docetaxel) in women with metastatic breast cancer (breast cancer that has spread to other parts of the body) and whose disease has progressed following intravenous (i.v.) chemotherapy with anthracyclines. Xeloda monotherapy is also indicated for treatment of patients with metastatic breast cancer that is resistant to other chemotherapy drugs such as paclitaxel and anthracyclines. Xeloda is licensed for the first-line

treatment of stomach cancer that has spread, in South Korea.

The most commonly reported adverse events with Xeloda include diarrhoea, abdominal pain, nausea, stomatitis and hand-foot syndrome.

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* The added CMP will include an enhanced (ECG and blood tests) cardiac assessment at baseline, cycle 1 and 2 and after completion of chemotherapy for all new patients entering the trial.

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