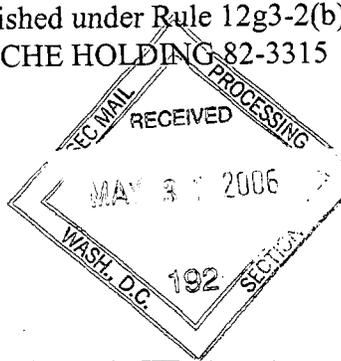


Roche - Investor Update

Investor Update

Basel, 24 May 2006



Roche



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### 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%<sup>1</sup> 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.<sup>2</sup> Similarly remarkable benefits have also been seen in three other major global and US studies.<sup>3</sup>

"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."

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 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,<sup>4</sup> and Genentech has received a priority review designation.

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**About the HERA study**

HERA, conducted by the Roche and Breast International Group (BIG),<sup>5</sup> 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.<sup>6</sup> 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.<sup>7</sup>

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 ([www.roche.com](http://www.roche.com)).

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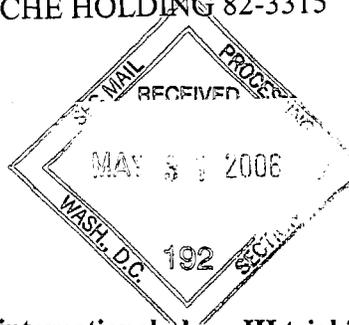
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Roche - Investor Update

Investor Update

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."

**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 (EMA) 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.

#### **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 ([www.roche.com](http://www.roche.com)).

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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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# Media Release



Basel, 29 May 2006

## **Herceptin added to hormonal therapy prolongs progression-free survival for patients with advanced HER2-positive breast cancer**

Roche announced today that data from a new study show that the addition of Herceptin (trastuzumab) to the hormonal therapy, Arimidex (anastrozole), increases the length of time that patients live without their cancer progressing (progression-free survival) for patients whose advanced breast cancer is hormone receptor-positive, as well as HER2-positive.

Hormone receptor-positive breast cancer affects two-thirds<sup>1</sup> of patients with breast cancer and is typically considered 'lower-risk' due to successful treatment with hormonal therapies. However, up to a quarter of these breast cancers are also HER2-positive,<sup>2</sup> an aggressive form of the disease that requires special and immediate attention because the tumours are fast-growing and there is a higher likelihood of relapse. This was the first randomised study in this specific subset of 'co-positive' patients, whose prognosis has been uncertain thus far.

Eduard Holdener, Global Head of Roche Pharma Development said: "We are glad to learn from this study that the combination therapy offers a new treatment regimen for these breast cancer patients who suffer from an extremely aggressive form of the disease. We will now work with trial investigators to analyse the full set of data from this trial, and submit it for presentation at an upcoming medical meeting in the second half of 2006. We will start preparations to file these data with health authorities around the world."

To date, over 230,000 patients with HER2-positive breast cancer have been treated with Herceptin worldwide. Herceptin consistently benefits patients regardless of whether it is given in the early stage or advanced settings, or whether it is in combination with chemotherapy, hormonal therapy, or as a single agent.

#### About the Study

The TANDEM study, conducted by Roche is a randomised, Phase III trial, which evaluated Herceptin plus Arimidex versus Arimidex alone as first-line therapy (or second line hormonal therapy) in postmenopausal women with advanced (metastatic), HER2-positive and hormone receptor-positive (ER-positive and/or PR-positive) breast cancer. Enrolment to the trial began in 2001, and 208 HER2 and hormone receptor co-positive patients were enrolled at 134 sites in 25 countries across the world. Arimidex was scheduled at a dose of 1 mg daily until progression. Herceptin was administered in 2 mg/kg weekly doses (after an initial loading dose of 4 mg/kg) until disease progression.

According to the analysis, the primary efficacy endpoint was met, showing that patients who received Herceptin had a statistically significant improvement in progression-free survival. Overall safety data in both arms of the trial were acceptable given the known safety profile of each of the drugs in the advanced breast cancer setting. 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.<sup>3</sup> 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%<sup>4</sup> 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.<sup>5</sup>

Herceptin received approval in the European Union in 2000 for use in patients with advanced (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 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 also received approval in the European Union in May 2006 for use in early-stage HER2-positive patients following standard chemotherapy.

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 ([www.roche.com](http://www.roche.com)).

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#### **Additional information:**

- About Genentech: [www.gene.com](http://www.gene.com)
- Roche in Oncology: [www.roche.com/pages/downloads/company/pdf/mboncology05e\\_b.pdf](http://www.roche.com/pages/downloads/company/pdf/mboncology05e_b.pdf)
- Roche Health Kiosk on cancer: [www.health-kiosk.ch/start\\_krebs](http://www.health-kiosk.ch/start_krebs)

To access video clips, in broadcast standard, free of charge, please go to: [www.thenewsmarket.com](http://www.thenewsmarket.com).

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# Media Release



Basel, 26 May 2006

## **Avastin Filed with FDA in US for Treatment of Women with Advanced Breast Cancer**

**Breakthrough therapy doubles the time women live without their breast cancer progressing**

Roche and Genentech announced today that they have filed Avastin (bevacizumab) in the US for the first line treatment of women with metastatic (advanced) breast cancer. Breast cancer is the leading cause of cancer death worldwide in women.

"The addition of Avastin to chemotherapy as a primary treatment for metastatic breast cancer doubled the time that women lived without their disease advancing compared to patients who received chemotherapy alone." said Eduard Holdener, Head of Roche Pharmaceuticals Development. "Breast cancer is now the third type of cancer where Avastin has shown a significant survival benefit. This submission marks an important milestone in our ongoing efforts to develop innovative therapies for breast cancer patients and to address unmet medical needs."

The supplemental Biologics License Application (sBLA) has been submitted to the US Food and Drug Administration (FDA) for use of Avastin in combination with standard chemotherapy (taxanes) for the first-line treatment of women with metastatic breast cancer. The submission is based on the impressive results of the pivotal E2100 Phase III trial which shows that, patients receiving Avastin plus paclitaxel had a median progression-free survival (PFS) of more than a year while patients receiving paclitaxel alone had a median PFS of approximately six months. A Marketing Authorisation Application (MAA) will be filed with the European Authorities later this year.

More than one million women are diagnosed with breast cancer each year worldwide and eight to nine percent of women are expected to develop breast cancer during their lifetime<sup>1</sup>. Breast cancer

is the leading cause of cancer death in women worldwide under the age of 55<sup>2</sup>, claiming more than 372,000 lives each year<sup>1</sup>.

Avastin is the first and only anti-angiogenic agent to have demonstrated improved overall and/or progression-free survival in the three important types of cancer: colorectal cancer, non-small cell lung cancer and breast cancer. In Europe, Avastin was approved early 2005 and in the USA in February 2004 for first-line treatment of patients with advanced colorectal cancer. Avastin was filed in April in the US for the most common form of lung cancer. The first filing for Avastin in Japan has been submitted last month for the treatment of advanced colorectal cancer.

#### About the E2100 study

This is the first phase III study to evaluate Avastin in combination with chemotherapy for first-line treatment of metastatic breast cancer. This randomised, controlled, multi-centre study enrolled 722 women with previously untreated metastatic breast cancer. The study was sponsored by the National Cancer Institute (NCI), part of the National Institutes of Health, and conducted by a network of researchers led by the Eastern Cooperative Oncology Group (ECOG). The patients were randomised to receive treatment with paclitaxel with or without Avastin. Avastin was given at a dose of 10mg/kg every two weeks until disease progression. The results showed that patients receiving Avastin plus paclitaxel had a median PFS of more than a year while patients receiving paclitaxel alone had a median PFS of approximately six months. Overall in the trial, patients treated with Avastin plus paclitaxel had a 52 percent reduction in the risk of disease progression or death, as expressed by a hazard ratio of 0.48 ( $1-0.48=0.52$  or 52%), which is also identical to doubling PFS ( $1/0.48 \approx 2$ ). Overall survival data for this trial are currently immature.

Patients with HER2-positive metastatic breast cancer were not enrolled in the study unless they had received prior treatment with Herceptin (trastuzumab) or were unable to receive treatment with Herceptin. Patients who had received adjuvant paclitaxel within the previous 12 months and patients with a prior history of blood clots or who were receiving blood thinners were also excluded from the study.

#### 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).

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

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<sup>1</sup> World Health Organisation (WHO) 2003. <http://www.who.int/mediacentre/releases/2003/pr27/en/>

<sup>2</sup> Brandy A. Box et al. Breast cancer. Manual of clinical oncology, fifth edition, 2004; 233-253