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Business Address
CH 4002
BASEL SWITZERLAND V8

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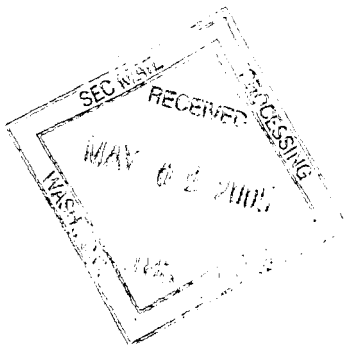

SUPPL

Basel, 28 April 2005

Herceptin: international study confirms significant improvement in disease-free survival for women with early-stage HER2-positive breast cancer

Interim analysis of HERA study based on almost 5,100 patients confirms Herceptin's potential to reduce risk of cancer coming back

Roche, Genentech and Breast International Group (BIG)[1] today announced that the interim analysis of HERA (HERceptin Adjuvant), a large scale, 39-country, phase III study with a wide range of chemotherapy regimens shows that the addition of Herceptin (trastuzumab) significantly increases disease-free survival for women with early-stage HER2-positive breast cancer.

These results come only two days after a joint interim analysis of two North American trials in early-stage breast cancer reported similarly impressive benefits for patients receiving Herceptin. These studies provide consistent evidence that Herceptin can reduce the risk of cancer coming back for women with early-stage HER2-positive breast cancer. HER2-positive breast cancer affects approximately 20 – 30% of women with breast cancer and is a particularly aggressive form of the disease which has a poor prognosis.[2]

"The combined data from over 8,000 patients analysed so far make a compelling case for Herceptin as an optimal treatment in HER2-positive early breast cancer and has potential to change the way breast cancer is managed," said William M. Burns, CEO of Roche's Pharmaceuticals Division. "This news represents an important milestone in the fight against this aggressive type of breast cancer and a real step forward for patients who previously faced a poor outlook. Based on these impressive results, we will work closely with health authorities around the world to make Herceptin accessible for early-stage HER2-positive breast cancer patients as soon as possible."

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F. Hoffmann-La Roche Ltd. CH-4070 Basel Corporate Communications
Tel. 061 - 688 88 88
Fax 061 - 688 27 75
http://www.roche.com

The HERA study, conducted by Roche and BIG, evaluated the use of Herceptin versus observation following a wide range of primary chemotherapy (chemotherapy given before or after surgery) and radiotherapy (if applicable). An interim analysis met its primary efficacy endpoint by showing that patients who received Herceptin had statistically significant improvement in disease-free survival (the length of time after treatment during which no disease is found). The secondary endpoint of overall survival has not yet been reached, possibly due to short follow up. Patients in the study will continue to be monitored, and an improvement in overall survival is possible to be achieved as the data mature. The HERA Steering Committee will work to submit data from this phase III trial for presentation at an upcoming medical meeting in 2005.

Dr Martine Piccart, Head of the Medicine Department at the Jules Bordet Institute in Brussels and lead investigator of the HERA study, commented, "To date, HERA is one of the biggest studies ever conducted among breast cancer patients, and we are very pleased that the study has shown such significant clinical benefits for this patient population. It is now crucial that testing for HER2 status becomes standard for all women at primary diagnosis of breast cancer to ensure that all women with HER2-positive disease have the chance to benefit from this important drug."

About the HERA study

Enrolment to the HERA trial began in December 2001, and nearly 5,100 patients have been enrolled at 480 sites in 39 countries across the world. HERA is a randomised trial which evaluates the use of standard adjuvant systemic chemotherapy and radiotherapy (if applicable) followed with or without Herceptin every three weeks for 12 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.

The interim analysis compared Herceptin versus observation and did not include a comparison of 12 months versus 24 months. These 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. 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.[1] 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. Herceptin 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. 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 disease, it is also indicated as a first-line therapy in combination with paclitaxel where anthracyclines are unsuitable, and as a single agent in second- and 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 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).

Further information:

- Herceptin: www.HER2status.com and www.herartrial.com
- Genentech: www.gene.com
- Cancer: www.health-kiosk.ch
- Roche in Oncology: www.roche.com/pages/downloads/company/pdf/mboncology05e_b.pdf

Media Relations Contacts:

Phone: +41 61 688 88 88 / e-mail: basel.mediaoffice@roche.com

- Baschi Dürr
- Alexander Klauser
- Daniel Piller (Head Roche Group Media Office)
- Katja Prowald (Head Science Communications)
- Martina Rupp

References:
1. Collaborative partners for the HERA study include: Roche, the Breast International Group (BIG) and its affiliated collaborative groups, plus non-affiliated collaborative groups, and independent sites
2. Harries M, Smith I. The development and clinical use of trastuzumab (Herceptin). Endocr Relat Cancer 9: 75-85, 2002.
3. World Health Organization, 2000