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Continuing Herceptin treatment prevents disease progression in women with aggressive metastatic breast cancer

Women with HER2-positive breast cancer benefit from nearly three extra months of life without progression

Basel, May 30 2008 – New data presented at the American Society for Clinical Oncology Annual Meeting (ASCO) demonstrate that Herceptin helps women with advanced (metastatic) HER2-positive breast cancer live longer without their cancer progressing. The final analysis of the randomized phase III GBG-26 study showed that Herceptin continued to work in women who needed additional treatment after their cancer progressed during previous Herceptin treatment.

Key findings of the study were:

- Herceptin plus Xeloda prolonged survival without progression of the cancer by nearly 3 months compared to chemotherapy alone (Time to progression from 5.6 to 8.2 months).
- In addition, continuation of Herceptin nearly doubled the percentage of patients responding to treatment from 27.0% to 48.0%.

GBG26 is the first randomized phase III study conducted in women with HER2-positive breast cancer that require additional treatment for their advanced disease and have received Herceptin as part of their initial therapy. The study reinforces that Herceptin works across all stages of the disease and confirms its position as the foundation of care for HER2-positive breast cancer.

“It is rewarding to see that trastuzumab keeps working in women whose aggressive HER2-positive breast cancer progresses” said lead investigator Prof. von Minckwitz, University Women’s Hospital, Frankfurt, Germany and Managing Director of the German Breast Group. “The GBG-26 study results confirm that trastuzumab continues to target and shrink the cancer even beyond progression when combined with another chemotherapy.”

Unfortunately, in the majority of women with advanced breast cancer the disease continues to spread after initial treatment and patients are likely to receive several subsequent courses (or lines) and types of therapy. However, advanced breast cancer still remains essentially an incurable disease. The GBG26 study therefore addressed a very important question – do patients whose disease has progressed receive benefit from Herceptin when given it again?

“The GBG-26 study adds to the existing strong evidence that Herceptin extends survival throughout all stages of HER2-positive breast cancer.” commented William M. Burns, CEO of Roche’s Pharmaceuticals Division, Basel, Switzerland “These results provide new hope for women whose breast cancer is difficult to treat.”

There is mounting evidence including the GBG-26 study confirming that Herceptin is the foundation of care for women with HER2-positive breast cancer. Herceptin works by activating the body’s own immune system to target and destroy the tumour, as well as by suppressing HER2. .

About GBG26

GBG-26 is a randomized phase III trial looking at Herceptin treatment in patients with HER2-positive metastatic breast cancer requiring a subsequent line of treatment.

Women with HER2-positive locally advanced or metastatic breast cancer who had previously received Herceptin with or without chemotherapy as first line treatment were randomly assigned to receive Herceptin (6 mg/kg body weight every 3 weeks) with Xeloda (2500 mg/m² on days 1-14, q 21), or Xeloda treatment alone. The primary end point was time to progression (TTP). The final analysis included 156 patients. GBG-26 showed good cardiac tolerability. TTP was increased from 5.6 months for Xeloda alone to 8.2 months in the Herceptin plus Xeloda. The p-value was p=0.034.

About breast cancer

Breast cancer is the most common cancer among women worldwide.ⁱ Each year more than one million new cases of breast cancer are diagnosed worldwide, and nearly 400,000 people will die of the disease annually.ⁱⁱ

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 percent of women with breast cancer.

About Herceptin (trastuzumab)

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. It has demonstrated efficacy in treating both early and advanced (metastatic) breast cancer. Given on its own as monotherapy as well as in combination with or following standard chemotherapy, Herceptin has been shown to improve response rates, disease-free survival and overall survival while maintaining quality of life in women with HER2-positive breast cancer.

Herceptin received approval for use in the European Union for advanced (metastatic) HER2-positive breast cancer in 2000, and for early HER2-positive breast cancer in 2006. In the advanced setting, Herceptin is now approved for use as a first-line therapy in combination with paclitaxel where anthracyclines are unsuitable, as first-line therapy in combination with docetaxel, and as a single agent in third-line therapy. It is also approved for use in combination with an aromatase inhibitor for the treatment of post-menopausal patients with HER2 and hormone receptor co-positive metastatic breast cancer. In the early setting, Herceptin is approved for use following standard (adjuvant) 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 more than 450,000 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 the world's biggest biotech company and an innovator of products and services for the early detection, prevention, diagnosis and treatment of diseases, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is the world leader in in-vitro diagnostics and drugs for cancer and transplantation, and is a market leader in virology. It is also active in other major therapeutic areas such as autoimmune diseases, inflammatory and metabolic disorders and diseases of the central nervous system. In 2007 sales by the Pharmaceuticals Division totalled 36.8 billion Swiss francs, and the Diagnostics Division posted sales of 9.3 billion francs. Roche has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai, and invested over 8 billion Swiss francs in R&D in 2007. Worldwide, the Group employs about 79,000 people. Additional information is available on the Internet at www.roche.com.

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Roche Group Media Relations

Phone: +41 -61 688 8888 / e-mail: basel.mediaoffice@roche.com

- Daniel Piller (Head)
- Alexander Klauser
- Martina Rupp
- Claudia Schmitt
- Nina Schwab-Hautzinger

i World Health Organization, <http://www.who.int/cancer/detection/breastcancer/en/>

ii Ferlay J, et al., GLOBOCAN 2002. Cancer Incidence, Mortality and Prevalence Worldwide. IARC CancerBase No.5, Version 2.0. IARC Press, Lyon, 2004. 2004