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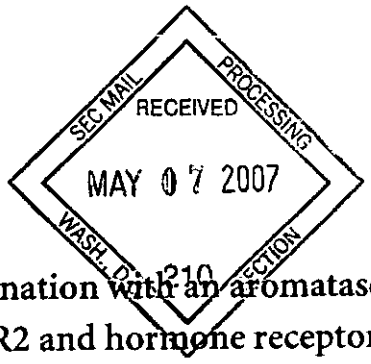

Basel, 3 May 2007

Herceptin approved in Europe for use in combination with an aromatase inhibitor for the treatment of patients with HER2 and hormone receptor-co-positive metastatic breast cancer

The first combination of targeted therapies for any cancer to receive approval worldwide

Roche announced today that the European Commission has approved the use of Herceptin in combination with an aromatase inhibitor for the treatment of postmenopausal patients with HER2 and hormone receptor co-positive metastatic breast cancer.

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The approval is based on data from the international phase III TAnDEM study which showed that the addition of Herceptin to hormonal therapy doubled the median progression-free survival (time patients live without their cancer progressing), from 2.4 months to 4.8 months.[1]
"Today's approval means that for the first time a combination of targeted therapies is available for patients who suffer from a particularly aggressive form of breast cancer," commented William M. Burns, CEO Division Roche Pharmaceuticals. "Herceptin consistently benefits patients regardless of whether it is given in the early- or advanced-stage settings, or whether it is in combination with chemotherapy, hormonal therapy, or as a single agent."

Comprehensive reviews have suggested that approximately two thirds of breast tumours are hormone receptor positive[2]. Of these, a significant percentage (up to 25%) are also HER2-positive.[3,4,5]. TAnDEM is the first randomised study to show that this specific subset of patients with 'co-positive' disease (both HER2- and hormone receptor-positive) are at an increased risk of relapse, making the positive results with Herceptin even more meaningful.

Herceptin is currently approved for the treatment of early and metastatic (advanced) HER2-positive disease, and has demonstrated a survival benefit in both settings. This new approval will also allow Herceptin to be used in combination with hormonal therapy for advanced breast cancer.

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About the TAnDEM study

TAnDEM, conducted by Roche, is a randomised phase III trial which evaluated Herceptin in combination with the hormonal therapy anastrozole versus anastrozole 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 patients with HER2 and hormone receptor co-positive disease were randomised at 77 centres in 22 countries across the world.

Median progression-free survival, the primary endpoint of the trial, was 4.8 months for patients who received the combination compared to 2.4 months for patients who received hormonal therapy alone ($p = 0.0016$). Patients in the combination arm also responded significantly better to treatment (overall response rate was 20.3% versus 6.8%; $p = 0.018$). There was also a positive trend in median overall survival (28.5 months versus 23.9 months; $p = 0.325$); this is despite the fact that in the hormonal therapy alone arm, more than half of patients (58/104) crossed over to receive Herceptin during the trial when their disease had progressed, and an additional 15 (out of 104) patients received Herceptin at a later time point.

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 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 breast cancer cases.

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 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 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. 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.

To date, nearly 400,000 patients with HER2-positive breast cancer have been treated with Herceptin 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, a market leader in virology and active in other major therapeutic areas such as autoimmune diseases, inflammation, metabolism and central nervous system. In 2006 sales by the Pharmaceuticals Division totalled 33.3 billion Swiss francs, and the Diagnostics Division posted sales of 8.7 billion Swiss francs. Roche employs roughly 75,000 worldwide 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 at www.roche.com.

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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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