Basel, 11 June, 2012

**FDA approves Perjeta (pertuzumab) for people with HER2-positive metastatic breast cancer**

New personalised medicine gives people with aggressive form of breast cancer more time without their disease worsening

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has approved Perjeta™ (pertuzumab). Perjeta is approved in combination with Herceptin® (trastuzumab) and docetaxel chemotherapy for the treatment of people with HER2-positive metastatic breast cancer (mBC) who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease. This approval is based on data from a Phase III study which showed that people with previously untreated HER2-positive mBC who received the combination of Perjeta, Herceptin and docetaxel chemotherapy lived a median of 6.1 months longer without their cancer getting worse (progression-free survival, or PFS) compared to Herceptin plus docetaxel chemotherapy (median PFS 18.5 vs. 12.4 months).

The combination of Perjeta, Herceptin and chemotherapy is the only regimen to have shown a significant improvement in progression free survival compared to Herceptin plus chemotherapy in people with previously untreated HER2-positive metastatic breast cancer.

Perjeta is a personalised medicine that targets the HER2 receptor, a protein found in high quantities on the outside of cells in HER2-positive cancers. Perjeta is believed to work in a way that is complementary to Herceptin, as the two medicines target different regions on the HER2 receptor.

“Today’s approval of Perjeta is an important advance in the treatment of HER2-positive metastatic breast cancer,” said Hal Barron, M.D., Chief Medical Officer and Head, Global Product Development. “Perjeta attacks HER2-positive tumors differently than Herceptin. Based on the way the two medicines work together, the combination plus chemotherapy can prolong the time before this aggressive cancer worsens compared to Herceptin and chemotherapy alone. We are very pleased to see our efforts in studying the science of HER2 translate into another personalized medicine.”
With the approval, Roche has agreed to post-marketing commitments related to the manufacturing process for Perjeta. These include FDA review of data from the next several productions of the medicine.

“We expect to meet demand for Perjeta following today’s FDA approval. We recently identified a cell growth issue that might affect our future supply of the medicine,” said Patrick Y. Yang, Ph.D., Head, Pharma Global Technical Operations. “We take this very seriously and are working with the FDA to ensure a consistent manufacturing process that maintains drug supply for the people who need it.”

Roche has also submitted a Marketing Authorisation Application to the European Medicines Agency (EMA) for Perjeta in combination with Herceptin and docetaxel chemotherapy for the treatment of previously untreated HER2-positive mBC or locally recurrent, unresectable (inoperable) breast cancer, in patients who have not received previous treatment or whose disease has returned after treatment in the early-stage setting. This application is currently under review by the EMA.

**About Perjeta**

Perjeta is designed specifically to prevent the HER2 receptor from pairing (or ‘dimerising’) with other HER receptors (EGFR/HER1, HER3 and HER4) on the surface of cells, a process that is believed to play a role in tumour growth and survival. Binding of Perjeta to HER2 may also signal the body’s immune system to destroy the cancer cells. The mechanisms of action of Perjeta and Herceptin are believed to complement each other, as both bind to the HER2 receptor, but to different regions. The combination of Perjeta, Herceptin and chemotherapy is thought to provide a more comprehensive blockade of HER signalling pathways.

**About the CLEOPATRA study**

CLEOPATRA (CLinical E valuation O f Pertuzumab A nd TRA stuzumab) is an international, Phase III, randomised, double-blind, placebo-controlled study. The study evaluated the efficacy and safety profile of Perjeta combined with Herceptin and docetaxel chemotherapy compared to Herceptin and chemotherapy plus placebo alone in 808 people with previously untreated HER2-positive mBC or that had recurred after prior therapy in the adjuvant or neoadjuvant setting. The study showed that patients who received Perjeta in combination with Herceptin and chemotherapy experienced a 38 percent reduction in the risk of their disease worsening or death compared to those who received placebo and Herceptin plus chemotherapy (HR=0.62; p-value less than 0.0001, according to independent review). The study demonstrated a 6.1-month
improvement in median PFS for patients who received Perjeta compared to those who received Herceptin and chemotherapy plus placebo (median PFS 18.5 vs. 12.4 months).

In CLEOPATRA, the most common adverse reactions (rate greater than 30 percent) seen with Perjeta in combination with Herceptin and docetaxel were diarrhea, hair loss, low white blood cell count, nausea, fatigue, rash and peripheral neuropathy (numbness, tingling or burning sensation in the arms or legs). The most common Grade 3–4 adverse reactions (rate greater than 2 percent) were low white blood cell count, low white blood cell count with fever, decrease in a certain type of white blood cell, diarrhea, peripheral neuropathy, decrease in red blood cell count, weakness and fatigue.

About breast cancer
Breast cancer is the most common cancer among women worldwide. Each year about 1.4 million new cases of breast cancer are diagnosed worldwide, and over 450,000 women will die of the disease annually. In HER2-positive breast cancer, increased quantities of the human epidermal growth factor receptor 2 (HER2) are present on the surface of the tumour cells. This is known as “HER2 positivity” and affects approximately 15-20 percent of women with breast cancer. HER2-positive cancer is a particularly aggressive form of breast cancer.

About Herceptin
Herceptin (trastuzumab) is a humanised monoclonal antibody, designed to target and block the function of HER2, a protein produced by a specific gene with cancer-causing potential when it is overexpressed. The mode of action of Herceptin is unique in that it activates the body’s immune system and suppresses HER2 signalling to target and destroy the tumour. Herceptin has demonstrated unprecedented efficacy in treating both early and advanced (metastatic) HER2-positive breast cancer. Given on its own as monotherapy as well as in combination with or following standard chemotherapy, Herceptin has been shown to improve overall survival, response rates and disease-free survival while maintaining quality of life in women with HER2-positive breast cancer. 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 1.2 million people with HER2-positive breast cancer worldwide.

About Roche
Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined
strengths in pharmaceuticals and diagnostics. Roche is the world’s largest biotech company with truly differentiated medicines in oncology, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche’s personalized healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2011, Roche had over 80,000 employees worldwide and invested over 8 billion Swiss francs in R&D. The Group posted sales of 42.5 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan. For more information: www.roche.com.

All trademarks used or mentioned in this release are protected by law.

Additional information
Roche in Oncology: www.roche.com/de/media/media_backgrounder/media_oncology.htm

Roche Group Media Relations
Phone: +41 61 688 8888 / e-mail: basel.mediaoffice@roche.com
- Alexander Klauser (Head)
- Silvia Dobry
- Daniel Grotzky
- Claudia Schmitt

References