Basel, July 15, 2011

**Pertuzumab combined with Herceptin and chemotherapy significantly extended the time people with HER2-positive metastatic breast cancer lived without their disease getting worse**

Roche plans to seek approval with Health Authorities based on encouraging results

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that CLEOPATRA, a pivotal Phase III study, met its primary endpoint. The study showed that people with HER2-positive metastatic breast cancer (mBC) who received the combination of two targeted medicines, pertuzumab and Herceptin® (trastuzumab), plus docetaxel chemotherapy lived significantly longer without their disease getting worse (progression-free survival, PFS) than people who received only Herceptin and docetaxel.

No new safety signals were observed and adverse events were consistent with those seen in previous studies of pertuzumab and Herceptin, either in combination or alone. Data from CLEOPATRA will be submitted for presentation at an upcoming medical meeting.

Despite significant progress, HER2-positive metastatic breast cancer remains an incurable disease. “These results with pertuzumab combined with Herceptin and docetaxel are very encouraging and represent our commitment to developing potential new personalised options for people with this aggressive disease,” said Hal Barron, M.D., chief medical officer and head, Global Product Development. “We plan to submit the study results for global regulatory approval this year.”

**About the CLEOPATRA study**

CLEOPATRA (**C**linical **E**valuation **O**f **P**ertuzumab **A**nd **T**rastuzumab) is a Phase III, randomised, double-blind, placebo-controlled clinical study evaluating the efficacy and safety profile of pertuzumab combined with Herceptin and docetaxel chemotherapy compared to Herceptin and docetaxel in people with HER2-positive mBC.
The two-arm study enrolled 808 people with previously untreated HER2-positive mBC from 19 countries worldwide.

- Participants in the pertuzumab arm received:
  - Docetaxel 75-100 mg/m² every three weeks for six cycles or until progression
  - Herceptin 8 mg/kg loading dose followed by 6 mg/kg every three weeks
  - Pertuzumab 840 mg loading dose followed by 420 mg every three weeks

- Participants in the Herceptin plus docetaxel arm received:
  - Docetaxel 75-100 mg/m² every three weeks for six cycles or until progression
  - Herceptin 8 mg/kg loading dose followed by 6 mg/kg every three weeks

The primary study endpoint was PFS as assessed by an independent review. Secondary endpoints are overall survival (OS), safety profile, overall response rate (ORR), duration of remission, quality of life and correlation of biomarkers with clinical outcomes.

**About pertuzumab**

Pertuzumab is a monoclonal antibody being studied in early-stage and metastatic HER2-positive breast cancer. It is an investigational HER2-targeted medicine called a HER2 dimerisation inhibitor (HDI). HER dimerisation (pairing) is believed to play an important role in the growth and formation of several different cancer types. Pertuzumab is the first investigational medicine developed to specifically prevent the HER2 receptor from pairing with other HER receptors (EGFR/HER1, HER3 and HER4). In doing so, pertuzumab is thought to block cell signalling, which may inhibit cancer cell growth or lead to the death of the cancer cell. The mechanisms of action of pertuzumab and Herceptin are believed to complement each other as both bind to the HER2 receptor but on different regions. The goal of combining pertuzumab with Herceptin and chemotherapy is to determine if the combination may provide a more comprehensive blockade of HER signalling pathways.

**About Breast Cancer**

Breast cancer is the most common cancer among women worldwide¹. Each year about 1.4 million new cases of breast cancer are diagnosed worldwide, and over 450,000 women will die of the disease annually². 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 15-25 percent of women with breast cancer³. HER2-positive cancer is a particularly aggressive form of breast cancer³.
About Herceptin
Herceptin is a monoclonal antibody, designed to target and block the function of HER2, a protein produced by a specific gene with cancer-causing potential. The mode of action of Herceptin is unique in that it activates the body’s immune system and suppresses HER2 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 response rates, disease-free survival and overall 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 almost 1 million patients 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 personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2010, Roche had over 80’000 employees worldwide and invested over 9 billion Swiss francs in R&D. The Group posted sales of 47.5 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.

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