Roche to present important new data for HER2-positive breast cancer at 2011 San Antonio Breast Cancer Symposium

Roche

Basel, 30 November 2011

Roche to present important new data for HER2-positive breast cancer at 2011 San Antonio Breast Cancer Symposium

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that it will present results from studies of its investigational medicine pertuzumab in HER2-positive breast cancer, at the 34th Annual CTRC-AACR San Antonio Breast Cancer Symposium (SABCS) December 6-10 2011. This includes data from the first randomised Phase III study of pertuzumab in combination with Herceptin and docetaxel chemotherapy (CLEOPATRA). 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.

“We are making additional substantial progress against HER2-positive breast cancer, a disease for which we have already dramatically changed the standard of care and improved patient outcomes," said Hal Barron, M.D., chief medical officer and head, Global Product Development. “Data at this conference reaffirm our commitment to discovering new treatments for HER2-positive breast cancer."

Data from the VIRGO metastatic breast cancer registry will also be presented. These emphasise the importance of accurate HER2 diagnostic testing in ensuring that the HER2 status of breast cancer is accurately identified, and that people subsequently receive appropriate treatment for their disease.

Key Study Results to be Presented at SABCS

Pertuzumab

- Full results from CLEOPATRA, a randomised Phase III pivotal study that compared the combination of pertuzumab, Herceptin® (trastuzumab) and docetaxel chemotherapy to Herceptin and chemotherapy alone in people with previously untreated HER2-positive metastatic breast cancer will be presented by Professor Jose Baselga, M.D., PhD, chief of Hematology/Oncology and Associate Director of the Massachusetts General Hospital Cancer Centre. Pertuzumab is an investigational medicine known as a HER2 dimerisation inhibitor (HDI). This is the first time progression-free survival (PFS) data from a randomised study of pertuzumab will be

presented, and study results will be featured in a SABCS press briefing.
CLEOPATRA: A Phase III, Randomized, Double-Blind, Placebo-Controlled Registration Trial to Evaluate the Efficacy and Safety of Pertuzumab + Trastuzumab + Docetaxel vs. Placebo + Trastuzumab + Docetaxel in Patients with Previously Untreated HER2-Positive Metastatic Breast Cancer (CLEOPATRA). (Abstract #S5-5). SABCS press briefing, Thursday 8 December, 07:30 CST. Oral presentation, General Session 5, Friday 9 December, 10:30 CST, Exhibit Hall D.

- Biomarker analyses from NEOSPHERE, a four-arm randomised Phase II neoadjuvant study evaluating the combination of pertuzumab, Herceptin and chemotherapy in people with newly-diagnosed, early-stage HER2-positive breast cancer will be presented by Luca Gianni, M.D., Director of Medical Oncology at the San Raffaele Cancer Center in Milan, Italy. At the 2010 SABCS, the NEOSPHERE data showed giving this combination to people in the neoadjuvant setting significantly improved the rate of complete tumour disappearance (pathological complete response rate, pCR) in the breast by more than half compared to Herceptin plus chemotherapy without pertuzumab.
  NEOSPHERE: Neoadjuvant pertuzumab (P) and trastuzumab (H): Biomarker analyses of a 4-arm randomized Phase II study ('NeoSphere') in patients (pts) with HER2-positive breast cancer (BC). (Abstract #S5-1). Oral presentation, General Session 5, Friday 9 December, 09:30 CST, Exhibit Hall D.
- Results from TRYPHAENA, a randomised Phase II neoadjuvant study investigating the combination of pertuzumab and Herceptin with or without an anthracycline-based chemotherapy regimen, will be presented by Professor Andreas Schneeweiss, Director of Gynecological Oncology at the National Centre for Tumor Diseases, University Hospital Heidelberg, Germany.
  TRYPHAENA: Neoadjuvant pertuzumab and trastuzumab concurrent or sequential with an anthracycline-containing regimen or concurrent with an anthracycline-free standard regimen: a randomized Phase II study (TRYPHAENA). (Abstract #S5-6). Oral presentation, General Session 5, Friday 9 December, 10:45 CST, Exhibit Hall D.

HER2 Testing

- Data from the VIRGO metastatic breast cancer registry will be presented. The results underscore the importance of accurate diagnostic testing, which could potentially impact treatment decisions for many people with breast cancer. Results being presented will specifically address rates of people misdiagnosed with HER2-negative breast cancer.
  VIRGO: Discordance between central and local laboratory HER2 testing from a large HER2-negative population in VIRGO, a metastatic breast cancer registry. (Abstract #P1-07-02). Poster Session 1, Prognosis/Response Predictions: Biomarkers – Methods, Wednesday 7 December, 17:00 CST, Exhibit Halls A-B.

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. Binding of pertuzumab to HER2 may also signal the body's immune system to destroy the cancer cells. 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 Herceptin

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. 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 as well as HER2-positive advanced (metastatic) stomach cancer. Given on its own as monotherapy as well as in combination with or following standard chemotherapy, Herceptin has been shown to improve disease-free survival overall survival and response rates while maintaining quality of life in people with HER2-positive breast and stomach 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 one million patients with HER2-positive breast and stomach cancer worldwide and is approved in more than 150 countries.

SOURCE [1]

Links:
[1] http://www.roche.com/media/media_releases/med-cor-2011-11-30.htm