Published on 12 December 2009, 11:10

Categories: Breast Cancer Cancer HER2 HER2-positive HER2-positive breast cancer Herceptin | More

Greater chances of cure for patients with HER2-positive early breast cancer when treated with one year of Herceptin

Herceptin long-term survival benefits and favourable safety profile confirmed by two pivotal studies.

Today, Roche (SIX: RO, ROG; OTCQX: RHHBY) announced new long-term follow up-data from two large pivotal studies evaluating adjuvant Herceptin in HER2-positive early- stage breast cancer presented at the San Antonio Breast Cancer Symposium (SABCS). Both studies, N9831 conducted by the North Central Cancer Treatment Group (NCCTG) and BCIRG006 performed by the Breast Cancer International Research Group consistently showed that Herceptin reduced the risk of the cancer returning by about one third in women with HER2-positive early breast cancer compared to patients receiving chemotherapy alone. In both studies, at least 80% of women receiving one year of Herceptin were alive free of the disease at 5 years follow-up.

“The course of this aggressive disease has been changed to the better, Herceptin is offering women with HER2 -positive breast cancer greater chances of cure.” said William M. Burns, CEO of Roche’s Pharmaceuticals Division. He continued by saying: “The long-term follow-up results from pivotal studies solidly confirm that one year of Herceptin is the foundation of care.”

The trials confirmed Herceptin’s favourable cardiac safety profile at long-term follow-up. In addition, both studies were seeking to answer questions the medical community has been contemplating regarding the best way of giving their patients Herceptin treatment.

N9831 is the only trial performed to study the impact of Herceptin administration either concurrently with or after chemotherapy. While the study clearly showed the long-term benefit of one year of Herceptin treatment with either regimen, there was a trend for the concurrent regimen being more beneficial to patients.

BCIRG006 evaluated Herceptin in combination with anthracycline-based chemotherapy versus an anthracycline free regimen. The study showed that both approaches extended survival without the cancer returning as well as overall survival compared to chemotherapy alone.

Dr Dennis Slamon, director of clinical/translational research at UCLA's Jonsson Comprehensive Cancer Center, highlighted “It is very rewarding to see that Herceptin provides survival benefits when given in combination with anthracycline-free chemotherapy, thereby offering a better cardiac safety profile compared to the combination with anthracycline containing therapy.”

About the N9831 study

N9831 is a US, Phase III, randomised, multicentre, open label trial of one year of adjuvant Herceptin.

Patients with HER2-positive early breast cancer were given either chemotherapy alone, Herceptin following chemotherapy (sequential) or Herceptin at the same time as chemotherapy (concurrent). The study was conducted by the North Central Cancer Treatment Group (NCCTG) with help of hundreds of sites in the US, Mayo Clinic in Jacksonville (Florida) being one of them. The trial was conducted with funding from the NCI, Genentech, and the BCRF (Breast Cancer Research Foundation). Dr. Perez is the Principal Investigator of the study.

The primary endpoint of the study was to demonstrate superiority in disease free survival of the Herceptin-containing treatment arms compared to the chemotherapy alone arm. The secondary endpoint of the study included overall survival.

The results of the study show that disease free survival is significantly improved with the addition of one year of Herceptin treatment (sequentially or concurrently) compared to chemotherapy alone. Patients who were treated with Herceptin had a 30% reduction in the risk of their cancer returning when compared to patients receiving chemotherapy alone. More than 80% of the patients receiving one year of Herceptin treatment were still alive free of disease at 5 year follow-up. The trial confirmed Herceptin’s favourable cardiac safety profile at long-term follow-up.

The N9831 study looked at Herceptin administration either concurrently with or after chemotherapy. Both regimens demonstrated the long-term benefit of one year of Herceptin treatment. Data from the concurrent arm showed that there was a trend for this regimen to be more beneficial to patients.

About the BCIRG 006 study

BCIRG 006 is an independent, Phase III randomised study designed to evaluate the use of two chemotherapies (docetaxel and carboplatin) when combined with Herceptin following initial adjuvant treatment with doxorubicin and cyclophosphamide chemotherapy for early HER2-positive breast cancer. The study was conducted by the Breast Cancer International Research Group (BCIRG).

The primary endpoint of the study was disease free survival and the secondary endpoints were overall survival, toxicity and pathologic and molecular markers for predicting efficacy.

The study showed that, when Herceptin was given in combination with an anthracycline-containing regimen, the risk of recurrence was reduced by 36% in women treated with one year Herceptin vs. chemotherapy alone and the risk of death was reduced by 37%. The results of the study also showed that, when Herceptin was given in combination with an anthracycline-free regimen, the risk of recurrence was reduced by 25% in women treated with one year of Herceptin vs. chemotherapy alone, and the risk of death was reduced by 23%. In both cases, the results were statistically significant. Regardless of the regimen used, at least 80% of

women receiving one year of Herceptin treatment were alive free of the disease at five years follow-up. The trial confirmed Herceptin's favourable cardiac safety profile at long-term follow-up.

About Herceptin

Herceptin is a humanized 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 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 650,000 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 2008, Roche had over 80,000 employees' worldwide and invested almost 9 billion Swiss francs in R&D. The Group posted sales of 45.6 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.

Contact: Roche Group Media Relations, Corporate Communications, CH-4070 Basel, Switzerland, Tel: +41-61 -688 8888, Fax: +41-61-688 2775, Send E-Mail

Source: Roche, F. Hoffmann-La Roche Ltd

Related News

Categories: Breast Cancer Cancer HER2 HER2-positive HER2-positive breast cancer Herceptin

Drug for Multiple Myeloma Demonstrated to Significantly Extend... 18 December 2009, 09:49
Initial results from a large, randomized clinical trial for patients with multiple myeloma, a...

UAB Researchers Link Calorie Intake to Cell Lifespan, Cancer... 18 December 2009, 06:37
BIRMINGHAM, Ala. - Researchers from the University of Alabama at Birmingham (UAB) have discovered...

New protein key for cell proliferation identified by McGill... 14 December 2009, 12:25
Study provides means for developing anti-cancer therapies.Researchers at McGill University have...

Antibody-guided drug shows encouraging activity in metastatic... 14 December 2009, 12:03
A new antibody-drug compound shrank or halted the growth of metastatic breast tumors in almost...

Tracking new cancer-killing particles with MRI 14 December 2009, 11:31
Nanoparticle could allow diagnosis, treatment in one visit.Researchers at Rice University and...

M. D. Anderson Study Questions True Favorability of Rare Breast... 14 December 2009, 09:01
In an era of minimalist therapy, some mucinous carcinoma patients may need more, not less,...

UGA Study finds significantly worse outcomes in cancer patients... 14 December 2009, 08:11
Athens, Ga. – A new study published by researchers from the University of Georgia and the...

GSK study showed targeted therapy combination achieved 14 month... 11 December 2009, 13:23
London UK, Philadelphia, PA – In a clinical study, women with an aggressive form of breast...

Experimental drug targets chemo-resistant breast cancer stem cells 11 December 2009, 09:29
HOUSTON -- (December 11, 2009) -- In animal and patient studies, an experimental drug eliminated...

Bacterial protein mimics its host to disable a key enzyme 11 December 2009, 05:52
Helicobacter pylori infects up to 90 percent of people in the developing world and causes gastric...