Media Release

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Embargoed until Friday 11th December 2009, 12:30 CST

Avastin plus commonly used chemotherapies improves time without the disease getting worse in women with previously treated advanced breast cancer

Results from RIBBON 2 study show potential new role for Avastin as second-line treatment in advanced breast cancer

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced results from a phase III study (RIBBON 2) of Avastin® (bevacizumab) in women with advanced HER2-negative breast cancer who had previously received chemotherapy as first-line treatment. The study showed that women who received Avastin in combination with commonly used chemotherapies as second-line treatment had a 28% improvement in the chance of being alive without the disease getting worse (progression-free survival or PFS) compared to chemotherapy alone. Adverse events were consistent with those previously reported for Avastin and no new Avastin safety findings were observed in the study.

This is a significant result as most women with advanced disease will see their cancer get worse when their initial chemotherapy stops working and currently, the only option for these women is subsequent chemotherapy.

“This is the first phase III study to show that the combination of an anti-angiogenic medicine with commonly used second-line chemotherapy can extend the time women with advanced breast cancer live without the disease worsening,” said Dr Adam Brufsky, M.D., Medical Director of the Women's Cancer Center, University of Pittsburgh Medical Center and principal investigator of the study.

RIBBON 2 is another positive phase III trial, adding to the clinical evidence for Avastin as a treatment for women with advanced breast cancer, this time in the second-line setting. The role of Avastin in the first-line setting is well established and supported by the results of three phase III studies of Avastin (E2100, AVADO and RIBBON-1). Overall, these studies show consistent efficacy and safety across patient sub-groups and independent of the chemotherapies Avastin was combined with.

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Key results from RIBBON 2 are:

- A 28% improvement in the chance of being alive without the disease getting worse (PFS), the primary endpoint of the study (Hazard Ratio= 0.78, p=0.0072).
- Women who received Avastin plus chemotherapy had a median PFS of 7.2 months compared to 5.1 months for those who received chemotherapy alone.
- The observed increase in tumour shrinkage in patients that received Avastin (response rate = 39.5% vs. 29.6% for Avastin + chemotherapy vs. chemotherapy alone) further supports the activity of Avastin in this setting (p=0.0193).

"Roche is committed to improving the lives of women with breast cancer, continuing to research whether the benefits of Avastin can be extended to broader groups of patients who need more treatment options," said William M. Burns, CEO of Roche's Pharmaceuticals Division. "This is another significant step for women with advanced breast cancer, and we look forward to sharing this data with healthcare authorities around the world."

RIBBON 2 was featured today during a press briefing at the 32nd Annual San Antonio Breast Cancer Symposium. Full results will be presented this afternoon (Abstract #42 – Friday, December 11, 2009, 3:00 p.m. – 3:15 p.m. CST, Exhibit Hall D).

About RIBBON 2 (AVF3693g)

RIBBON 2 is an international, multicentre, randomised, double-blind, placebo-controlled clinical study that enrolled 684 patients with previously treated metastatic HER2-negative breast cancer. The trial evaluated the combination of either Avastin or placebo with an investigator's choice of chemotherapy. Avastin was administered every two or three weeks until disease progression. The following chemotherapy regimens were used in the study:

- Taxanes: paclitaxel, protein-bound paclitaxel or docetaxel
- Gemcitabine
- Capecitabine
- Vinorelbine

The primary endpoint of the study was PFS. PFS was defined as the time from randomisation to disease progression or death as assessed by the treating physicians in the study (investigator-assessed). The study met its primary endpoint of showing a statistically significant and clinically

meaningful improvement in PFS with the combination of Avastin with commonly used second-line chemotherapy.

Secondary endpoints included objective response rate, one-year survival rate, overall survival, PFS assessment by chemotherapy type and safety.

About Avastin

Avastin is an antibody that specifically binds and blocks the biological effects of VEGF (vascular endothelial growth factor). VEGF is a key driver of tumour angiogenesis – an essential process required for a tumour to grow and to spread (metastasize) to other parts of the body. Avastin's precise mode of action allows it to be combined effectively with a broad range of chemotherapies and other anti-cancer treatments. Avastin helps to control tumour growth and extend survival with only a limited impact on the side effects of chemotherapy.

Avastin has proven survival benefits across several types of cancer. It is approved in Europe for the treatment of the advanced stages of four common types of cancer: colorectal cancer, breast cancer, non-small cell lung cancer (NSCLC) and kidney cancer. These types of cancer collectively cause over 2.5 million deaths each year[1,2,3]. In the US, Avastin was the first anti-angiogenesis therapy approved by the FDA and it is now approved for the treatment of five tumour types: colorectal cancer, non-small cell lung cancer, breast cancer, brain (glioblastoma) and kidney (renal cell carcinoma).

Over half a million patients have been treated with Avastin so far. A comprehensive clinical programme with over 450 clinical trials is investigating the use of Avastin in various tumour types (including colorectal, breast, non-small cell lung, brain, gastric, ovarian, prostate and others) and different settings (advanced or early stage disease).

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.

Additional information

- About cancer: www.roche.com/cancer.htm
- B-Roll and visuals can be found at: www.thenewsmarket.com

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References

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3. Parkin DM et al. CA Cancer J Clin 2005; 55: 74-108.