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

**RIBBON-2: The first phase III study to show progression-free survival benefit of Avastin as second-line treatment for advanced breast cancer**

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that a Phase III study of Avastin (bevacizumab) in combination with a range of chemotherapies met its primary endpoint of increasing the time women with previously treated advanced HER2 negative breast cancer lived without the disease getting worse (progression-free survival or PFS) compared to chemotherapy alone. In the RIBBON-2 study, investigators chose the type of chemotherapy used in combination with Avastin and the chemotherapies were assessed together in the primary endpoint analysis. No new Avastin safety signals were observed in the study. Data from the study will be submitted for presentation at a future medical meeting.

“This is good news for women with advanced breast cancer as nearly all women require additional therapy after their initial treatment,” said William M. Burns, CEO of Roche’s Pharmaceuticals Division. “RIBBON-2 is the first phase III study to show that Avastin may also offer benefits in the second-line setting, and we look forward to sharing the data with healthcare authorities around the world.”

In March 2007, Avastin was approved in Europe for the first-line treatment of patients with advanced breast cancer, in combination with paclitaxel. The European licence was recently extended in July 2009 to allow combination with another commonly used taxane based chemotherapy called docetaxel. Avastin was also approved in combination with paclitaxel in the US in February 2008 under the Food and Drug Administration's (FDA) accelerated approval programme, which allows provisional approval of medicines for cancer or other life-threatening diseases.

Despite the treatment improvements that have already been made, breast cancer continues to be the leading cause of cancer death in women under age of 55. More than one million women are diagnosed with breast cancer each year, this leading to over 500,000 deaths from the disease worldwide.<sup>1,2</sup>

### **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 addition of either Avastin or placebo to an investigator's choice of chemotherapy. 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). 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 VEGF (vascular endothelial growth factor). VEGF is the key driver of tumour angiogenesis – an essential process of development and maintenance of blood vessels which is required for a tumour to grow and to spread (metastasize) to other parts of the body. Avastin's precise mode of action helps control tumour growth and metastases with only a limited impact on side effects of chemotherapy.

Avastin has proven survival benefits across multiple tumour types. Avastin 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.<sup>3,4,5</sup> In the US, Avastin was the first anti-angiogenesis therapy approved by the FDA and 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).

More than 500,000 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).

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