

Basel, 18th November 2011

FDA Commissioner Announces Final Decision on Avastin for Metastatic Breast Cancer

- **U.S. Food and Drug Administration (FDA) Commissioner revokes approval of Avastin for treatment of metastatic breast cancer (mBC) in the United States**
- **This action concludes the FDA's review of Avastin's use for mBC**
- **This decision does not impact Avastin's approved uses for other cancer types in the United States or other countries**
- **This decision also does not impact the approval of Avastin for mBC in more than 80 other countries**
- **Roche will start a new trial of Avastin plus paclitaxel in mBC**

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the FDA Commissioner is revoking the approval of Avastin® (bevacizumab) for the treatment of mBC in the United States.

“We are disappointed with the outcome. We remain committed to the many women with this incurable disease and will continue to provide help through our patient support programs to those who may be facing obstacles to receiving their treatment in the United States,” said Hal Barron, M.D., chief medical officer and head, Global Product Development. “Despite today’s action, we will start a new Phase III study of Avastin in combination with paclitaxel in previously untreated metastatic breast cancer and will evaluate a potential biomarker that may help identify which people might derive a more substantial benefit from Avastin.”

About Avastin: Over 5 Years of Transforming Cancer Care

With the initial approval in the USA for advanced colorectal cancer in 2004, Avastin became the first anti-angiogenic therapy made widely available for the treatment of patients with an advanced cancer.

Today, Avastin is continuing to transform cancer care through its proven survival benefit (overall survival and/or progression free survival) across several types of cancer. Avastin is approved in the US and Europe for

the treatment of advanced stages of colorectal cancer, breast cancer, non-small cell lung cancer and kidney cancer, and Avastin is also available in the US and over 32 other countries for the treatment of patients with glioblastoma (a type of brain cancer). Avastin is the only anti-angiogenic therapy available for the treatment of these numerous advanced cancer types, which collectively cause over 2.5 million deaths each year.

Avastin has made anti-angiogenic therapy a fundamental pillar of cancer treatment today – over one million patients have been treated with Avastin so far. A comprehensive clinical programme with more than 500 ongoing clinical trials is investigating the use of Avastin in over 50 tumour types (including colorectal, breast, non-small cell lung, brain, gastric, ovarian and others) and different settings (advanced or early stage disease).

About Avastin: Mode of Action

Avastin is an antibody that specifically binds and blocks the biological effects of VEGF (vascular endothelial growth factor). VEGF is the key driver of tumour angiogenesis – a fundamental process required for a tumour to grow and to spread (metastasise) 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.

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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Additional information

- Roche in Oncology: www.roche.com/media/media_backgroundunder/media_oncology.htm

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