

Basel, 12 March, 2010

Roche provides update on phase III study of Avastin in men with late stage prostate cancer

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today the topline results of a phase III trial led by the US Cancer and Leukemia Group B (CALGB) and sponsored by the National Cancer Institute investigating the use of Avastin (bevacizumab) in combination with docetaxel chemotherapy and prednisone in men with late stage prostate cancer (hormone-refractory / HRPC). The study, known as CALGB 90401, did not meet its primary objective of extending overall survival compared to chemotherapy and prednisone alone. A preliminary assessment of safety performed by CALGB has shown adverse events that have been previously observed in pivotal trials with Avastin. Data from the study will be submitted by CALGB for presentation at the 2010 American Society of Clinical Oncology (ASCO) annual meeting, June 4 to 8, 2010.

“Patients with hormone-refractory prostate cancer are in urgent need of new treatment options. It is unfortunate that the study did not meet its primary objective, however, we look forward to sharing the data with the medical community, including the secondary endpoints,” said Hal Barron, M.D., Head Global Development and Chief Medical Officer at Roche.

These findings do not impact Avastin’s approved indications, where Avastin has made anti-angiogenic therapy a fundamental pillar of cancer treatment. Avastin’s broad development programme in other tumour types will also continue as planned.

About prostate cancer

Prostate cancer is the second most commonly diagnosed cancer in men worldwide only after lung cancer, with over 679,000 men receiving a diagnosis of the disease each year. One third of men diagnosed – almost 200,000, will die from their disease.¹

About CALGB 90401

CALGB 90401 is a multicentre, randomized, double-blinded, placebo-controlled phase III study designed to evaluate Avastin plus docetaxel chemotherapy and prednisone compared to docetaxel chemotherapy and prednisone alone in 1,050 men with hormone-refractory prostate cancer. The trial is sponsored by the National Cancer Institute (NCI) under a Cooperative Research and Development Agreement between the NCI and Genentech, and conducted by a network of researchers led by the CALGB.

The primary endpoint of the study is overall survival. Secondary endpoints of the study include progression-free survival, prostate-specific antigen response rate, and safety.

Detailed safety assessments are ongoing. A preliminary assessment of safety performed by CALGB has identified severe adverse events that have been previously observed in pivotal trials with Avastin, including neutropenia and fatal infections.

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 for the treatment of patients with advanced brain cancer (glioblastoma). 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 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 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 2009, Roche had over 80'000 employees worldwide and invested almost 10 billion Swiss francs in R&D. The Group posted sales of 49.1 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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References

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