Roche study showed that adding Avastin to radiation and chemotherapy significantly extended the time people with an aggressive form of brain cancer lived without their disease worsening

The Phase III AVAglio study met its co-primary endpoint of significantly improving progression-free survival in people with glioblastoma.

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the phase III AVAglio study of Avastin plus radiation and temozolomide chemotherapy in people with newly diagnosed glioblastoma met its co-primary endpoint of a significant improvement in progression-free survival (PFS). In the study, Avastin in combination with radiation and temozolomide chemotherapy significantly extended the time people with this aggressive form of primary brain cancer lived without their disease getting worse (PFS), compared to those treated with radiation and temozolomide chemotherapy plus placebo. Data for final overall survival (OS), the other co-primary endpoint, are expected in 2013.

No new safety findings were observed in the AVAglio study and adverse events were consistent with those seen in previous trials of Avastin across tumour types for approved indications. Full data from the AVAglio study will be submitted for presentation at an upcoming medical meeting.

“This study showed that people with glioblastoma, a particularly devastating and aggressive cancer without many treatment options, lived significantly longer without their disease worsening when Avastin was added to radiation and temozolomide chemotherapy,” said Hal Barron M.D., Chief Medical Officer and Head Global Product Development.

Avastin is currently approved in the United States and over 30 countries worldwide for the treatment of glioblastoma as a single agent and in some countries in combination with irinotecan for adult patients with progressive disease following prior therapy (relapsed setting). The approval in the USA was granted under the Food and Drug Administration’s (FDA) accelerated approval programme.
Roche plans to discuss these phase III results with global regulatory authorities, including the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA).

**About the AVAglio study**

AVAglio is a phase III, randomised, double blind, placebo controlled trial that assessed the efficacy and safety profile of Avastin in combination with radiation and temozolomide chemotherapy following surgery or biopsy in patients with newly diagnosed glioblastoma. Patients were randomised to receive either:

- Avastin plus radiation and temozolomide chemotherapy for six weeks followed by a four-week break. Patients then received Avastin and temozolomide for up to six cycles, followed by Avastin alone until disease progression.
- Radiation, temozolomide and placebo for six weeks followed by a four-week break. Patients then received temozolomide and placebo for up to six cycles, followed by placebo until disease progression.

The co-primary endpoints of the study were OS and PFS as assessed by trial investigators. Secondary endpoints included one- and two-year survival rates, PFS as assessed by an independent review committee, safety profile, and quality of life measures.

**About glioblastoma**

Glioma (cancer of the glial cells) is the most common type of malignant primary brain tumour (a tumour that originates in the brain), accounting for approximately one third of all cases diagnosed. Glioblastoma (or glioblastoma multiforme; GBM) is the most common and the most aggressive type of glioma. Glioblastoma affects approximately 13,000 people per year in the EU. Glioblastoma is a rational therapeutic target for Avastin as these tumours have among the highest levels of vascular endothelial growth factor (VEGF) of any solid tumour.

**About Avastin: Over 8 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 Europe for the treatment of advanced stages of breast cancer, colorectal cancer, non-small cell lung cancer, kidney cancer and ovarian cancer, and is available in the USA for the treatment of colorectal cancer, non-small cell lung cancer.
cancer and kidney cancer. In addition, Avastin is approved in the USA and over 30 other countries for the treatment of patients with progressive glioblastoma following prior therapy. Avastin is approved in Japan for the treatment of the advanced stages of colorectal, non-small cell lung cancer and breast 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.

**About Avastin: Mode of Action**

An independent blood supply is critical for a tumour to grow beyond a certain size (2mm) and spread (metastasise) to other parts of the body. Tumours develop their own blood supply in a process called angiogenesis by releasing vascular endothelial growth factor (VEGF) – a key driver for tumour growth. Avastin is an antibody that precisely targets and inhibits VEGF for continuous tumour control. Avastin’s precise VEGF inhibition allows it to be combined effectively with a broad range of chemotherapies and other anti-cancer treatments with limited additional impact on the side effects of these therapies.

**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 personalized healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2011, Roche had over 80,000 employees worldwide and invested over 8 billion Swiss francs in R&D. The Group posted sales of 42.5 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.

All trademarks used or mentioned in this release are protected by law.
Additional information

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

Roche Group Media Relations
Phone: +41 61 688 8888 / e-mail: basel.mediaoffice@roche.com
- Alexander Klauser (Head)
- Silvia Dobry
- Daniel Grotzky

References
1. Decision Resources, Cancer Incidence in 5 Continents Version IX, CI5 IX, World Population Prospects, Central Brain Tumor Registry of the United States, National Swedish Brain Tumour Registry.