Media Release

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Roche's Avastin receives broader EU label for women with metastatic breast cancer

Expanded label allows combination with Xeloda or paclitaxel in first-line setting

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the European Commission has extended the existing Avastin (bevacizumab) metastatic breast cancer label to include combination with Xeloda (capecitabine). The European Commission had recently confirmed the approval of Avastin in combination with paclitaxel chemotherapy for women with metastatic breast cancer in the first-line setting. This new extension provides an additional first-line treatment option for women in whom treatment with other chemotherapies (including taxanes or anthracyclines) is not considered appropriate.

The label extension was based on data from the phase III RIBBON 1 study which showed a significant increase in the length of time women lived without their disease getting worse (progression-free survival) when Avastin was combined with capecitabine compared to those who received capecitabine alone. Adverse events in RIBBON1 were consistent with those seen in previous pivotal trials of Avastin across tumor types.

"The decision received from the EU Commission supports our belief that Avastin provides a clinically meaningful benefit in combination with Xeloda," said Hal Barron M.D., Chief Medical Officer and Head, Global Product Development. "We are pleased with this outcome because it means that women with metastatic breast cancer and their physicians will now have an additional treatment option in Europe."

Data from the pivotal E2100 (Avastin and paclitaxel) study forms the basis of Avastin's licensed combination with paclitaxel in metastatic breast cancer. This showed that Avastin in combination with paclitaxel chemotherapy doubled median progression-free survival (PFS) compared with paclitaxel alone. Some chemotherapy options including taxanes and anthracyclines are not always appropriate for all women with metastatic breast cancer. The approval of this broader label will give these women an additional first-line therapy choice.

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Results from the RIBBON 1 study of Avastin in combination with capecitabine showed:

- A 45 percent increase in the likelihood of women being alive without disease progression compared to those who received capecitabine alone (hazard ratio=0.69; p=0.0002).
- A median PFS of 8.6 months compared to 5.7 months in those women that received capecitabine alone.
- 35.4% of women experienced a major shrinkage of their tumor compared to 23.6% of those receiving capecitabine alone (p= 0.0097).

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 tumor 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 tumor angiogenesis – a fundamental process required for a tumor 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 tumor growth and extend survival with only a limited impact on the side effects of chemotherapy.

About Xeloda (capecitabine)

Xeloda (capecitabine) is a highly effective targeted oral chemotherapy offering patients a survival advantage when taken on its own or in combination with other anticancer drugs. Xeloda uniquely activates the cancer-killing agent 5-FU (5-fluorouracil) directly inside the cancer cells. Xeloda tablets can be taken by patients in their own home, reducing the number of hospital or clinic visits.
Licensed and marketed by Roche in more than 100 countries worldwide, Xeloda has over 11 years proven clinical experience providing an effective and flexible treatment option to over 1.8 million people with cancer. Xeloda is currently approved in:

Metastatic Breast Cancer

- Monotherapy in patients with tumors resistant to taxanes and anthracyclines – (US) 1998 and (EU) 2002
- In combination with docetaxel in patients whose disease has progressed following IV chemotherapy with anthracyclines – (US) 2001 and (EU) 2002
- In patients with inoperable or recurrent breast cancer – (Japan) 2003

Metastatic Colorectal Cancer

- Monotherapy first-line (US , EU and ROW) – 2001
- In combination with any chemotherapy in all lines of treatment with or without Avastin (EU/ROW) – 2008
- In combination with oxaliplatin for the treatment of patients with advanced or refractory colorectal cancer who are not candidates for curative surgery (Japan) – 2009

Adjuvant Colon Cancer

- Monotherapy (US & EU) – 2005
- Monotherapy (Japan) – 2007
- In combination with oxaliplatin as XELOX (EU) – 2010

Advanced Gastric Cancer

- First-line treatment (South Korea) – 2002
- In combination with platinum-based chemotherapy first-line (EU and ROW) – 2007

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.

Additional information

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

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