Media Release

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Roche announces data to show Avastin based regimen halved the risk of disease getting worse in women with recurrent ovarian cancer

Phase III OCEANS results add to the growing body of evidence supporting Avastin's potential role in ovarian cancer

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced results from OCEANS, a phase III study evaluating Avastin (bevacizumab) in combination with chemotherapy (gemcitabine and carboplatin) followed by the continued use of Avastin alone in women with previously treated (recurrent) platinum-sensitive ovarian cancer. Women who received Avastin experienced a 52 percent reduction in the risk of their disease progressing (HR = 0.48, $p<0.0001$) compared to women who received chemotherapy alone. Adverse events in OCEANS were consistent with those seen in previous pivotal trials of Avastin across tumor types.

These results were featured in a press briefing today at the 47th Annual Meeting of the American Society of Clinical Oncology. Full results will be presented in the ASCO Gynecologic Cancer session by Dr. Carol Aghajanian, the OCEANS Principal Investigator and M.D., Chief, Gynecologic Medical Oncology Service, [Memorial Sloan-Kettering Cancer Center, New York] (Abstract LBA5007, 4 June, 4:15pm CDT).

"Women with recurrent ovarian cancer need new treatment options, and it is therefore an important advance to halve the risk of disease progression in this incurable cancer," said Hal Barron, M.D., Chief Medical Officer and Head Global Product Development. "These data add to the growing body of evidence supporting Avastin's potential role in this disease, which includes two previously presented phase III clinical trials in women with newly diagnosed ovarian cancer."

In OCEANS, women with recurrent, platinum-sensitive ovarian cancer, who received Avastin in combination with chemotherapy followed by continued use of Avastin alone until disease progression, experienced the following results:

- A median progression-free survival (PFS; the time without the disease progressing) of 12.4 months compared to 8.4 months in women who received chemotherapy alone

F. Hoffmann-La Roche Ltd 4070 Basel Switzerland
Group Communications Roche Group Media Relations
Tel. +41 61 688 88 88 Fax +41 61 688 27 75 www.roche.com

- Tumor shrinkage (Overall Response Rate) in 79 percent of women receiving the Avastin-based regimen compared to 57 percent of women who received chemotherapy alone.

Select adverse events (Grade 3-5) that occurred more often in the Avastin arm compared to the chemotherapy alone arm were hypertension (high blood pressure; 17 percent vs. <1 percent), proteinuria (an excess of protein in the urine; 9 percent vs. 1 percent) and bleeding that does not occur in the central nervous system (6 percent vs. 1 percent). Notably, there were no gastrointestinal perforations (a hole in the stomach or intestine) seen during the safety reporting period of this study.

About the OCEANS Study

OCEANS is a multicentre, randomized, double-blind, placebo-controlled phase III study in 484 women with platinum-sensitive recurrent ovarian, primary peritoneal or fallopian tube cancer. Women in OCEANS had received no more than one treatment regimen prior to enrolment in the trial. The trial was designed to evaluate Avastin (15mg/kg every three weeks) in combination with carboplatin and gemcitabine chemotherapy, followed by Avastin as a single agent until disease progression, or unacceptable toxicity, compared to placebo in combination with carboplatin and gemcitabine chemotherapy, followed by placebo alone. The primary endpoint of the study was progression-free survival. The secondary endpoints of the study included overall survival, objective response, duration of response and safety profile.

About Ovarian Cancer

Ovarian cancer is the eighth most commonly diagnosed cancer in women and the seventh leading cause of cancer death among women worldwide. Annually, over 220,000 women will be diagnosed with ovarian cancer around the world and approximately 140,000 will die from the disease.[i] Surgery to remove as much of the tumor as possible is a mainstay of treatment but unfortunately, the majority of patients are diagnosed with late stage disease (when the cancer has grown or spread) and they require further treatment.

Ovarian cancer is associated with high concentrations of vascular endothelial growth factor (VEGF), a protein associated with tumor growth and spread. Studies have shown a correlation between a high concentration of VEGF and ascites development (excess fluid in the body cavity), disease worsening, and a poorer prognosis in women with ovarian cancer. Avastin is designed to specifically target VEGF.

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 25 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 (metastasize) 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 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

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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

Claudia Schmitt

References:

[i] WHO, IARC GLOBOCAN, Cancer Incidence and Mortality Worldwide in 2008