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Roche

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Positive CHMP opinion is an important milestone towards making Avastin available for a disease where few treatment advances have been seen in over a decade

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for the use of Avastin in combination with standard chemotherapy (carboplatin and paclitaxel) as a front-line treatment for women with advanced ovarian cancer.

Ovarian cancer is the most deadly of the gynaecological cancers and approximately 140,000 women die from the disease each year. In a setting with few advances in the last decade, Avastin has demonstrated in two phase III studies (GOG0218 and ICON7) that those women who received the combination of Avastin and chemotherapy and then continued on Avastin alone, lived significantly longer without their disease getting worse (progression-free survival) compared to those who received chemotherapy only.

“The positive CHMP opinion is great news for women with advanced ovarian cancer, who need more effective treatment options,” said Hal Barron M.D., Chief Medical Officer and Head, Global Product Development. “Approval of Avastin would be a major development in this setting where few treatment advances have been seen in over a decade.”

The CHMP has supported the use of Avastin in combination with carboplatin and paclitaxel for the front-line treatment of advanced (FIGO stages IIIB, IIIC and IV) epithelial ovarian, primary peritoneal or fallopian tube carcinoma. Avastin is administered for 6 cycles of treatment followed by continued use of Avastin as single agent until disease progression or for a maximum of 15 months. The recommended dose of Avastin is 15 mg/kg of body weight given once every 3 weeks as an intravenous infusion.

Final approval from the European Commission is expected later this year.

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.[1] Surgery to remove as much of the tumour 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.

Avastin in Ovarian Cancer: Research Programme

Roche has an extensive research and clinical trial programme investigating Avastin in patients with ovarian cancer in both the front-line and recurrent setting (when the cancer has returned after initial therapy), in order to help improve treatment outcomes for women with ovarian cancer.

Avastin has so far demonstrated a significant improvement in the time women with ovarian cancer live without the disease getting worse (progression free survival; PFS) in three large phase III studies (GOG 0218 and ICON7 in the front-line setting and OCEANS in the recurrent, platinum-sensitive setting). Roche is committed to establishing the full potential of Avastin in ovarian cancer through continued research with other agents and in other settings.

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.

SOURCE [1]

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http://www.chem.info/news/2011/09/roche-039s-avastin-receives-positive-opinion-european-authority-treatment-women-newly-diagnosed-advanced-ovarian-cancer

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[1] http://www.roche.com/media/media_releases/med-cor-2011-09-23.htm