Roche & #039;s personalized medicine Zelboraf receives positive opinion from European authority for the treatment of people with BRAF mutation-positive metastatic melanoma

Roche

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Roche medicine Avastin receives EU approval for the treatment of women with newly diagnosed, advanced ovarian cancer

Avastin represents first major treatment advance for women with ovarian cancer in 15 years

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the European Commission has approved Avastin (bevacizumab) in combination with standard chemotherapy (carboplatin and paclitaxel) as a front-line (first-line following surgery) treatment for women with advanced ovarian cancer.

Ovarian cancer is the most deadly of the gynaecological cancers, with approximately 220,000 women diagnosed and 140,000 women dying from the disease each year globally. The approval of Avastin marks a major advance in the treatment of women with ovarian cancer for whom treatment has been limited to surgery and chemotherapy.

“Today’s approval of Avastin marks the first major treatment advance in newly diagnosed ovarian cancer in 15 years,” said Hal Barron M.D., Chief Medical Officer and Head, Global Product Development. “This is the fifth tumor type for which Avastin has been approved in Europe, making it one of few biologic drugs indicated for multiple cancers."

Avastin has demonstrated in two phase III studies (GOG0218 and ICON7) that women with newly diagnosed advanced ovarian cancer who received Avastin plus 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.

Ovarian cancer is associated with high concentrations of vascular endothelial growth factor (VEGF), a protein associated with tumour growth and spread. Avastin precisely inhibits VEGF, high levels of which are associated with ascites development (excess fluid in the body cavity), disease worsening, and a poorer prognosis in ovarian cancer patients.

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 tumor as possible, followed by chemotherapy, 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).

This approval will enable 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 cancer for women in Europe. Avastin is administered in addition to chemotherapy for up to 6 cycles of treatment followed by continued use of Avastin as single agent until disease progression or for a maximum of 15 months or until unacceptable toxicity, whichever occurs earlier. The recommended dose of Avastin is 15mg/kg of bodyweight given once every 3 weeks as an intravenous infusion.

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 Europe for the treatment of advanced stages of breast cancer, colorectal cancer, non-small cell lung cancer and kidney cancer, and is also available in the US for the treatment of colorectal cancer, non-small cell lung cancer and kidney cancer. In addition, Avastin is approved in the US and over 30

other countries for the treatment of patients with glioblastoma (a type of brain cancer). Avastin is also approved in Japan for the treatment of inoperable or recurrent 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 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.

SOURCE [1]

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[1] http://www.roche.com/media/media_releases/med-cor-2011-12-23.htm