Roche & #039;s Avastin receives positive opinion from EU authority for the treatment of women with recurrent, platinum-sensitive ovarian cancer

Roche

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Positive CHMP opinion is another important milestone towards making Avastin available for women with ovarian cancer

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 (bevacizumab) in combination with chemotherapy (carboplatin and gemcitabine) as a treatment for women with recurrent, platinum-sensitive ovarian cancer.

Ovarian cancer has the highest mortality rate of all gynaecological cancers. Almost 230,000 women worldwide are diagnosed with this cancer each year, many of them with advanced disease that returns after initial treatment. Patients are said to have ‘platinum-sensitive’ disease if their ovarian cancer returns more than six months after completion of the last platinum-based chemotherapy. In platinum sensitive disease, Avastin has demonstrated in a phase III study (OCEANS) that those women who received the combination of Avastin and chemotherapy and then continued 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 encouraging news for women with recurrent ovarian cancer, a disease where few treatment advances have been made over the past decade,” said Hal Barron M.D., Roche’s Chief Medical Officer and Head of Global Product Development. “An approval for women with recurrent disease would be another significant advance following Avastin's approval last year for the treatment of women with newly diagnosed ovarian cancer.”

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.

The CHMP has supported the use of Avastin in combination with carboplatin and gemcitabine for the treatment of adult patients with the first recurrence of platinum sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor targeted agents. Avastin is administered in combination with carboplatin and gemcitabine chemotherapy for 6 cycles and up to 10 cycles followed by continued use of Avastin as single agent until disease progression. The recommended dose of Avastin is 15 mg/kg of body weight given once every 3 weeks as an intravenous infusion.

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. Each year, an estimated 230,000 women are diagnosed with ovarian cancer around the world, and approximately 140,000 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. Patients are said to have ‘platinum-sensitive’ disease if their ovarian cancer returns more than six months after completion of the last platinum-based chemotherapy. Women are considered to have ‘platinum-resistant’ ovarian cancer if the disease comes back less than six months after completing prior platinum-based chemotherapy.

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

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 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 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.

SOURCE [1]

Links:
[1] http://www.roche.com/media/media_releases/med-cor-2012-09-21.htm