Roche drug Avastin approved in Switzerland for treatment of advanced cervical cancer

Avastin in combination with chemotherapy helps women with this type of cancer live longer than with chemotherapy alone.

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the Swiss regulatory and supervisory authority (Swissmedic) approved Avastin (bevacizumab) in combination with chemotherapy for the treatment of women with persistent, recurrent or metastatic cervical cancer.¹ This means that Avastin is now authorised in Switzerland for the treatment of seven different types of cancer.

“Early-stage cervical cancer is often still curable, whereas sadly the advanced disease has a very poor prognosis. Hence prevention through vaccination of young girls before their first sexual contact must be the first priority. The disease often affects young women – some of whom still have young children – for whom there are few treatment options when the disease has reached an advanced stage. This is why the approval of bevacizumab for advanced cervical cancer is so significant. A bevacizumab-based combination regimen shows a median survival benefit of four months and is likely to establish itself as standard therapy in the next few years,” said Prof. Viola Heinzelmann, Medical Director for Gynecology / Gynecological Oncology at University Hospital Basel.

About cervical cancer

Just over 240 new cases of cervical cancer are diagnosed in Switzerland every year. Thanks to extensive preventive measures, the incidence in Switzerland is only half that in Germany, but mortality is relatively high at approximately 35%.² Survival rates for cervical cancer very much depend on the stage of the disease at diagnosis. At least nine out of 10 women will live for five years following diagnosis of early-stage disease but the survival rate drops to below one in six women when the disease has spread to other parts of the body (metastasis).
Worldwide it is estimated that there are more than half a million cases of cervical cancer each year. There are over 250,000 deaths from the disease annually, making it the fourth leading cause of cancer death in women around the world.³

**About the GOG-0240 study**

The approval was based on the GOG-0240 study. GOG-0240 is an independent US National Cancer Institute (NCI)-sponsored study of the Gynecologic Oncology Group (GOG) that assessed the efficacy and safety profile of Avastin plus chemotherapy (paclitaxel and cisplatin or paclitaxel and topotecan) in women with persistent, recurrent or metastatic cervical cancer. Study data from 452 women showed:

- The study met its primary endpoint of improving overall survival (OS) with a statistically significant 29 percent reduction in the risk of death for women who received Avastin plus chemotherapy compared to those who received chemotherapy alone (median OS: 17.0 months vs. 13.3 months; Hazard Ratio (HR) = 0.71, p = 0.004).
- The study showed women who received Avastin plus chemotherapy had a significantly higher rate of tumour shrinkage (objective response rate, ORR) compared to chemotherapy alone (48 percent vs. 36 percent).
- Hypertension (high blood pressure) of Grade 2 or higher was significantly more common with Avastin-containing regimens (25 percent vs. 2 percent, p < 0.001), but no patients discontinued Avastin because of hypertension. Grade 3 or higher thrombosis (blood clots) was significantly increased with the Avastin-containing regimens (8 percent vs. 1 percent, p = 0.0001). Grade 3 or higher gastrointestinal-vaginal fistulas (abnormal passage from one part of the body to the other) occurred in 6 percent of patients receiving Avastin-containing regimens compared to less than 1 percent with chemotherapy alone (p=0.002). All of these patients had a history of pelvic radiation. Patients who develop these fistulas may require additional surgery. Grade 2 or higher gastrointestinal events (without fistulas) occurred in 52 percent of patients receiving Avastin, compared with 44 percent receiving chemotherapy alone (p = 0.10).
- Grade 4 or higher neutropenia was significantly increased with the Avastin-containing regimens (35 percent vs. 26 percent, p = 0.04).
- There was no increase in treatment-related deaths in the Avastin plus chemotherapy arm compared to the chemotherapy alone arm.
About Avastin – 10 years of transforming cancer care

Avastin has made anti-angiogenic therapy a fundamental pillar of cancer treatment today – over 1.4 million patients worldwide 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.

With the initial approval in the United States for advanced colorectal cancer in 2004, Avastin became the first anti-angiogenic cancer treatment available for the treatment of patients with 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. In addition, Avastin is approved in Switzerland and over 60 other countries worldwide for the treatment of patients with progressive glioblastoma following prior therapy.

About Avastin – mechanism of action

An independent blood supply is critical for a tumour to grow beyond a certain size (2 mm) and spread (metastatise) to other parts of the body. Tumours develop their own blood supply by forming new blood vessels 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. Precise VEGF inhibition by Avastin 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.

About Roche

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