Basel, 08 April 2015

**EU approves Roche’s Avastin plus chemotherapy for women with advanced cervical cancer**

Avastin is the first treatment in nearly a decade to extend the life of women with this advanced disease

Roche (SIX: RO, ROG, OTCQX, RHHBY) announced today that the European Commission (EU) approved Avastin (bevacizumab) in combination with standard chemotherapy (paclitaxel and cisplatin or, alternatively, paclitaxel and topotecan in patients who cannot receive platinum therapy) for the treatment of adult patients with persistent, recurrent or metastatic carcinoma of the cervix.¹

Unlike the majority of cancers, cervical cancer is most commonly diagnosed in younger women, between the ages of 35 and 44.² Each day it is estimated that 90 women are diagnosed with cervical cancer in Europe, and around 35 of these women will die from the disease.³ Avastin’s EU approval in persistent, recurrent or metastatic carcinoma of the cervix is an important development in a disease area where, until now, treatment options were limited to chemotherapy.

“We are pleased that women in Europe now have a much needed new treatment option that is proven to help them live longer lives compared to chemotherapy alone,” said Sandra Horning, M.D., Chief Medical Officer and Head of Global Product Development. “Currently, fewer than one in six women with this disease are alive five years after diagnosis. Avastin’s approval is a welcome advance for women with persistent, recurrent or metastatic carcinoma of the cervix”.

The EU approval was based on the significant survival benefit in the pivotal GOG-0240 study, which showed that women who received Avastin plus chemotherapy had a statistically significant 26 percent reduction in the risk of death, representing a median improvement in survival of nearly four months, compared to women who received chemotherapy alone (median overall survival: 16.8 months vs. 12.9 months; Hazard Ratio (HR)=0.74, p=0.0132).¹
Also based on the GOG-0240 data, Avastin in combination with paclitaxel and cisplatin or paclitaxel and topotecan chemotherapy was approved in the U.S. in August 2014, in Switzerland in December 2014, and in six other countries worldwide, for the treatment of women with persistent, recurrent or metastatic carcinoma of the cervix.

**About the GOG-0240 study**

GOG-0240 is an independent, National Cancer Institute (NCI)-sponsored study of the Gynecological 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 carcinoma of the cervix.

Study data from 452 women showed:

- The study met its primary endpoint of improving overall survival (OS) with a statistically significant 26 percent reduction in the risk of death, representing a median gain in survival of 3.9 months, compared with those who received chemotherapy alone (median overall survival: 16.8 months vs. 12.9 months; (HR)=0.74, p=0.0132).1
- The study showed that women who received Avastin plus chemotherapy had a significantly higher rate of tumour shrinkage (objective response rate, ORR) compared with those who received chemotherapy alone (45 percent [95% CI: 0.39%-0.52%] vs. 34 percent [95% CI 0.28%-0.40%]).1
- Overall, the safety profile in the study was consistent with that seen in previous pivotal studies of Avastin across tumour types, except for an increase in gastrointestinal-vaginal fistulae observed in patients who received Avastin plus chemotherapy compared to those who received chemotherapy alone (8.3% vs. 0.9% respectively). All patients with gastrointestinal-vaginal fistulae after treatment with Avastin plus chemotherapy had a history of prior pelvic radiation.1

**About cervical cancer**

It is estimated that over 33,000 women will be diagnosed with cervical cancer in the EU this year and about 13,000 women will die from the disease.3 While the chances of survival are higher if the disease is caught early (at least nine out of 10 women survive for five years or longer following early diagnosis), the symptoms of early-stage cervical cancer can be easily missed, and many women are not diagnosed until their cancer has already progressed to an advanced stage.2,4 At this stage, the survival rates are reduced and fewer than one in six women survive for five years or longer.2,4

Worldwide, it is estimated there are more than half a million cases of cervical cancer every year and over
260,000 deaths from the disease, making it the fourth leading cause of cancer death in women globally.\textsuperscript{5}

**About Avastin**
With the initial approval in the United States 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, ovarian cancer, and now cervical cancer, and is available in the United States for the treatment of colorectal cancer, non-small cell lung cancer, kidney cancer, cervical cancer and platinum-resistant, recurrent ovarian cancer. In addition, Avastin is approved in the United States and over 60 other countries worldwide for the treatment of patients with progressive glioblastoma following prior therapy. Avastin is approved in Japan for the treatment of the advanced stages of colorectal, non-small cell lung cancer, breast cancer, ovarian cancer and malignant glioma, including newly diagnosed glioblastoma.

Avastin has made anti-angiogenic therapy a fundamental pillar of cancer treatment today. Over 1.5 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.

**About Avastin – mechanism of action**
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. 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**
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, immunology, infectious diseases, ophthalmology and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner
in diabetes management. Roche’s personalised healthcare strategy aims at providing medicines and
diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded
in 1896, Roche has been making important contributions to global health for more than a century. Twenty-
four medicines developed by Roche are included in the World Health Organization Model Lists of Essential
Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.

In 2014, the Roche Group employed 88,500 people worldwide, invested 8.9 billion Swiss francs in R&D and
posted sales of 47.5 billion Swiss francs. Genentech, in the United States, is a wholly owned member of the
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1. Roche data on file