FDA grants Roche’s Avastin full approval for most aggressive form of brain cancer

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) has granted full approval for Avastin® (bevacizumab) for the treatment of adults with glioblastoma that progressed following prior therapy (referred to as recurrent disease). Avastin was previously granted provisional approval in this setting under the FDA’s accelerated approval program.

“Glioblastoma is the most common and aggressive form of brain cancer and can be very difficult to treat,” said Sandra Horning, M.D., chief medical officer and head of Global Product Development. “Delaying disease progression and reducing the need for corticosteroids over the course of treatment are considered important goals for those impacted by this devastating disease where patients have limited treatment options.”

This conversion to full approval was based on the totality of evidence of Avastin in glioblastoma, including data from the Phase III EORTC 26101 study. Avastin is now approved in the United States for nine distinct uses across six different types of cancer.

About the EORTC 26101 Study

EORTC 26101 is an independent Phase III, multicenter, randomized, open-label trial, conducted by the European Organization for Research and Treatment of Cancer (EORTC), which evaluated the addition of Avastin to lomustine chemotherapy in 432 patients with previously treated glioblastoma. The primary endpoint of the study was overall survival (OS), and progression-free survival (PFS) as assessed by investigator and overall response rate (ORR) were key secondary endpoints. Results showed the following:

- There was no significant increase in OS with Avastin-based treatment (HR=0.91, p=0.4578).
  - As the primary endpoint was not met, all secondary endpoints should be considered descriptive only.
- Avastin-based treatment increased the time to disease progression or death compared to chemotherapy alone (median PFS: 4.2 months vs. 1.5 months, HR=0.52, 95% CI: 0.41-0.64).
- Among people taking corticosteroids at baseline (50 percent), more people were able to completely stop intake of corticosteroids while on treatment in the Avastin arm compared to the control arm (23 percent vs. 12 percent).
- In the Avastin with lomustine arm, 22 percent of people discontinued treatment due to adverse reactions compared with 10 percent of people in the lomustine arm.
- Adverse events were consistent with those seen in previous trials of Avastin across tumor types for approved indications.

**About Glioblastoma**
Glioma (cancer of the glial cells) is the most common type of malignant primary brain tumor (a tumor that originates in the brain), and represents nearly one-fourth of all primary brain tumors and three-fourths of all malignant tumors. Glioblastoma (or glioblastoma multiforme) is the most common and the most aggressive type of glioma, accounting for more than half of all gliomas. It is estimated that more than 12,300 people will be diagnosed with glioblastoma in the United States in 2017.

**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 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 recurrent, platinum-resistant and platinum-sensitive ovarian cancer. In addition, Avastin is approved over 70 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 cancer, non-small cell lung cancer, cervical 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 2.7 million patients have been treated with Avastin so far. A comprehensive clinical programme with more than 300 ongoing clinical trials is investigating the use of Avastin in over 50 tumour types.
About Roche
Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people’s lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Roche is the world’s largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. Thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry nine years in a row by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2016 employed more than 94,000 people worldwide. In 2016, Roche invested CHF 9.9 billion in R&D and posted sales of CHF 50.6 billion. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

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