FDA accepts Roche’s supplemental Biologics License Application for Avastin as a front-line treatment for women with advanced ovarian cancer

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) has accepted the company’s supplemental Biologics License Application (sBLA) for Avastin® (bevacizumab) in combination with chemotherapy (carboplatin and paclitaxel), followed by Avastin alone, for the front-line treatment of women with advanced ovarian cancer.

“About 80 percent of women with ovarian cancer are diagnosed in the advanced stages when the disease is difficult to treat and options are limited,” said Sandra Horning, M.D., chief medical officer and head of Global Product Development. “We are committed to working closely with the FDA to bring this potential new treatment option to women with newly diagnosed advanced ovarian cancer as soon as possible.”

This sBLA for Avastin, in combination with carboplatin and paclitaxel, followed by Avastin as a single agent, for the front-line treatment of people with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, is based on data from the pivotal Phase III GOG-0218 trial. In newly diagnosed advanced ovarian cancer, the first treatment a woman receives after surgery is known as front-line treatment. The FDA is expected to make a decision on approval by June 25, 2018.

This is part of our broader development program for Avastin in ovarian cancer. Avastin is currently approved for treating two different forms of advanced disease that recurred after platinum-based chemotherapy. In addition, Genentech is evaluating Avastin in combination with ‘Tecentriq’ (atezolizumab) and chemotherapy for the treatment of newly diagnosed advanced ovarian cancer in the Phase III IMagyn050 trial (NCT03038100).
About the GOG-0218 Study
GOG-0218 (NCT00262847) is a multi-center, randomized, double-blind, placebo-controlled Phase III study in 1,873 women with previously untreated advanced epithelial ovarian, primary peritoneal, or fallopian tube carcinoma who already had surgery to remove as much of the tumor as possible. Participants were randomized into one of three treatment arms: chemotherapy alone (carboplatin and paclitaxel), Avastin (15 mg/kg) plus chemotherapy followed by placebo alone, or Avastin plus chemotherapy followed by Avastin alone. Women who received Avastin in combination with chemotherapy, and continued use of Avastin alone for a total duration of 22 cycles, had a median progression-free survival (PFS) of 18.2 months compared to 12.0 months in women who received chemotherapy alone (HR=0.64; 95% CI 0.54 - 0.77, p<0.0001). Secondary endpoints of the study included overall survival (OS) and objective response rate (ORR). Adverse events were consistent with those seen in previous trials of Avastin across tumor types for approved indications. The study was conducted by the Gynecologic Oncology Group (GOG) and their initial results were previously published in the New England Journal of Medicine.

About Ovarian Cancer
Ovarian cancer causes more deaths among women than any other gynecologic cancer in the United States. In 2017, nearly 22,000 women will be diagnosed with ovarian cancer in the U.S. and more than 14,000 will die from the disease. About 80% of ovarian cancer cases are found at an advanced stage, when the cancer has spread beyond the ovaries. Early ovarian cancer often does not have any symptoms and when symptoms, such as abdominal swelling, bloating, abdominal pain, difficulty eating or feeling full quickly, and/or frequent urination, are present, they can be associated by other less serious conditions. Five-year survival rates worsen dramatically based on stage of diagnosis.

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, 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 two 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

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