FDA Approves Genentechâ€™s Avastin (Bevacizumab) Plus Chemotherapy as a Treatment for Women With Advanced Ovarian Cancer Following Initial Surgery

â€“ Avastin is now approved for ten distinct uses across six different types of cancer in the United States â€“

Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY), today announced that the U.S. Food and Drug Administration (FDA) has approved AvastinÂ® (bevacizumab) in combination with chemotherapy (carboplatin and paclitaxel), followed by Avastin as a single agent, for the treatment of women with advanced (stage III or IV) ovarian cancer following initial surgical resection.

â€œTodayâ€™s approval is an important advance for women newly diagnosed with this type of ovarian cancer,â€• said Sandra Horning, M.D., chief medical officer and head of Global Product Development. â€œWeâ€™re committed to advancing medicines in areas of unmet need and this FDA approval of Avastin plus chemotherapy gives women with advanced ovarian cancer a new treatment option that has been shown to significantly delay disease progression or death.â€•

â€œThis approval represents an important milestone as the first medicine, other than chemotherapy, for women with advanced ovarian cancer after their initial surgery,â€• said David Barley, chief executive officer, National Ovarian Cancer Coalition (NOCC). â€œOvarian cancer is the fifth leading cause of cancer-related deaths among women in the United States, and this approval underscores Genentechâ€™s dedication to bringing new treatment options to women with gynecological cancers.â€•

The approval for Avastin, in combination with carboplatin and paclitaxel, followed by Avastin as a single agent, for the treatment of women with stage III or stage IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial surgical resection, is based on data from the pivotal Phase III GOG-0218Â trial. Women who received Avastin in combination with chemotherapy, and continued use of Avastin alone, had a median progression-free survival (PFS) of 18.2 months compared to 12.0

months in women who received chemotherapy alone (HR=0.62; 95% CI 0.52 - 0.75, p<0.0001). This PFS benefit was achieved with a fixed-duration treatment (up to 22 cycles of Avastin total). Avastin has boxed warnings for GI perforation, surgery and wound healing complications and hemorrhage.

Avastin is now approved for ten distinct uses across six different types of cancer in the United States. This indication represents Avastinâ€™s fourth gynecologic oncology indication in four years, including advanced cervical cancer and two different forms of ovarian cancer that recurred after platinum-based chemotherapy.

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 stage III or IV epithelial ovarian, primary peritoneal, or fallopian tube carcinoma who already had surgery to remove as much of the tumor as possible.Â 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 for a total of up to 22 cycles. The primary endpoint of the study was investigator-assessed PFS and secondary endpoints included overall survival (OS). The study was conducted by the Gynecologic Oncology Group (GOG) and initial results were previously published in the New England Journal of Medicine.

Â	GOG-0218 Study Results	Study Group
Â	Avastin with chemotherapy followed by Avastin alone	(N=623)
Â	Avastin with chemotherapy	(N=625)
Â	Chemotherapy alone	(N=625)

Progression-free survival (PFS, primary endpoint) Median PFS (months) Â 18.2 Â 12.8 Â 12.0 Hazard ratio (95% CI)1

Â 0.62 (0.52, 0.75) Â 0.83 (0.70, 0.98) Â Â pâ€“value2 Â < 0.0001 Â Not significant Â Â

Overall survival (OS, secondary endpoint)3 Median OS (months) Â 43.8 Â 38.8 Â 40.6 Hazard ratio (95% CI)1 Â 0.89 (0.76, 1.05) Â 1.06 (0.90, 1.24) Â Â Safety

Grade 3-4 adverse events occurring more often (â‰¥2%) in the Avastin with chemotherapy followed by Avastin alone arm or the Avastin with chemotherapy arm versus the chemotherapy alone arm were fatigue (9%, 6%, 6%, respectively), high blood pressure (10%, 6%, 2%), decreased platelet count (21%, 20%, 15%) and decreased white blood cell count (51%, 53%, 50%).

1 Relative to the control arm; stratified hazard ratio

2 Two-sided p-value based on re-randomization test

3 Final overall survival analysis

About Ovarian Cancer

Ovarian cancer causes more deaths among women than any other gynecologic cancer in the United States. In 2018, more than 22,000 women will be diagnosed with ovarian cancer in the U.S. and about 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 with other less serious conditions. Five-year survival rates worsen dramatically based on stage of diagnosis.

About Genentech Access Solutions

Access Solutions is part of Genentechâ€™s commitment to helping people access the Genentech medicines they are prescribed, regardless of their ability to pay. The team of in-house specialists at Access Solutions is dedicated to helping people navigate the access and reimbursement process, and to providing assistance to eligible patients in the United States who are uninsured or cannot afford the out-of-pocket costs for their medicine. To date, the team has helped more than 1.5 million patients access the medicines they need. Please contact Access Solutions (866) 4ACCESS/(866) 422-2377 or visit http://www.Genentech-Access.com for more information.

About Avastin

Avastin is a prescription-only medicine that is a solution for intravenous infusion. It is a biologic antibody designed to specifically bind to a protein called vascular endothelial growth factor (VEGF) that plays an important role throughout the lifecycle of the tumor to develop and maintain blood vessels, a process known as angiogenesis. Avastin is designed to interfere with the tumor blood supply by directly binding to the VEGF protein to prevent interactions with receptors on blood vessel cells. The tumor blood supply is thought to be critical to a tumor's ability to grow and spread in the body (metastasize).

Avastin Indications:

Metastatic colorectal cancer (mCRC) for first- or second-line treatment in combination with intravenous 5-fluorouracilâ€“based chemotherapy. It is also approved to treat mCRC for second-line treatment, when used with fluoropyrimidine-based (combined with irinotecan or oxaliplatin) chemotherapy, after cancer progresses following a first-line treatment that includes Avastin.

Avastin is not approved for use after the primary treatment of colon cancer that has not spread to other parts of the body Advanced nonsquamous nonâ€“small cell lung cancer (NSCLC) in combination with carboplatin and paclitaxel, in people who have not received chemotherapy for their advanced disease Metastatic kidney cancer (mRCC) when used with interferon alfa Glioblastoma (GBM) in adult patients whose cancer has progressed after prior treatment (recurrent or rGBM) Advanced cervical cancer (CC) in combination with paclitaxel and cisplatin or paclitaxel and topotecan, is approved to treat persistent, recurrent, or metastatic cancer of the cervix Ovarian cancer (OC). Avastin, in combination with carboplatin and paclitaxel,

followed by Avastin alone, is used for the treatment of patients with advanced (Stage III or IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial surgery.Avastin in combination with paclitaxel, pegylated liposomal doxorubicin or topotecan, is approved to treat platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer (prOC) in women who received no more than two prior chemotherapy treatments.Avastin, either in combination with carboplatin and paclitaxel or with carboplatin and gemcitabine, followed by Avastin alone, is approved for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer (psOC) Possible serious side effects

Everyone reacts differently to Avastin therapy. So, itâ€™s important to know what the side effects are. Although some people may have a life-threatening side effect, most do not. Their doctor will stop treatment if any serious side effects occur. Patients should contact their health care team if there are any signs of these side effects.

Most serious side effects (not common, but sometimes fatal):

GI perforation. A hole that develops in the stomach or intestine. Symptoms include pain in the abdomen, nausea, vomiting, constipation, or fever Wounds that donâ€™t heal. A cut made during surgery can be slow to heal or may not fully heal. Avastin should not be used for at least 28 days before or after surgery and until surgical wounds are fully healed Serious bleeding. This includes vomiting or coughing up blood; bleeding in the stomach, brain, or spinal cord; nosebleeds; and vaginal bleeding. If a patient has recently coughed up blood or had serious bleeding, they should be sure to tell their doctor Other possible serious side effects

Abnormal passage in the body. This type of passageâ€”known as a fistulaâ€”is an irregular connection from one part of the body to another and can sometimes be fatal Severe high blood pressure. Blood pressure that severely spikes or shows signs of affecting the brain. Blood pressure should be monitored every 2 to 3 weeks while on Avastin and after stopping treatment Kidney problems. These may be caused by too much protein in the urine and can sometimes be fatal Infusion reactions. These were uncommon with the first dose (less than 3% of patients). 0.2% of patients had severe reactions. Infusion reactions include high blood pressure or severe high blood pressure that may lead to stroke, trouble breathing, decreased oxygen in red blood cells, a serious allergic reaction, chest pain, headache, tremors, and excessive sweating. The patientâ€™s

doctor or nurse will monitor for signs of infusion reactions Severe stroke or heart problems. These may include blood clots, mini-stroke, heart attack, chest pain, and the heart may become too weak to pump blood to other parts of the body (congestive heart failure). These can sometimes be fatal Nervous system and vision problems. Signs include headache, seizure, high blood pressure, sluggishness, confusion, and blindness Side effects seen most often

In clinical studies across different types of cancer, some patients experienced the following side effects:

High blood pressure Too much protein in the urine Nosebleeds Rectal bleeding Back pain Headache Taste change Dry skin Inflammation of the skin Inflammation of the nose Watery eyes Avastin is not for everyone

Patients should talk to their doctor if they are:

Undergoing surgery. Avastin should not be used for 28 days before or after surgery and until surgical wounds are fully healed Pregnant or think they are pregnant. Data have shown that Avastin may harm a womanâ€™s unborn baby. Birth control should be used while patients are on Avastin. If Avastin is stopped, patients should keep using birth control for 6 months before trying to become pregnant Planning to become pregnant. Taking Avastin could cause a womanâ€™s ovaries to stop working and may impair her ability to have children Breastfeeding. Breastfeeding while on Avastin may harm the baby and is therefore not recommended during and for 6 months after taking Avastin Patients should talk with their doctor if they have any questions about their condition or treatment.

Report side effects to the FDA at (800) FDA-1088 orÂ http://www.fda.gov/medwatch.

Report side effects to Genentech at (888) 835-2555.

For full Prescribing Information and Boxed WARNINGS on Avastin please visitÂ http://www.avastin.com.

About Genentech

Founded more than 40 years ago, Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes medicines to treat patients with serious or life-threatening medical conditions. The company, a member of the Roche Group, has headquarters in South San Francisco, California. For additional information about the company, please visit http://www.gene.com.

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