FDA Approves Avastin Plus Chemotherapy for Ovarian Cancer

Bevacizumab approved for women with Stage III or IV cancer after surgery.

June 13, 2018 By Food and Drug Administration (FDA)

FDA approves bevacizumab in combination with chemotherapy for ovarian cancer

On June 13, 2018, the Food and Drug Administration approved bevacizumab (Avastin, Genentech, Inc.) for patients with epithelial ovarian, fallopian tube, or primary peritoneal cancer in combination with carboplatin and paclitaxel, followed by single-agent bevacizumab, for stage III or IV disease after initial surgical resection.

Approval was based on GOG-0218 (NCT00262847), a multicenter, randomized, double-blind, placebo-controlled, three-arm study evaluating the addition of bevacizumab to carboplatin and paclitaxel for patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial surgical resection. Patients (n=1,873) were randomized (1:1:1) to carboplatin plus paclitaxel without bevacizumab, carboplatin plus paclitaxel with bevacizumab for up to six cycles, or carboplatin plus paclitaxel with bevacizumab for six cycles followed by single-agent bevacizumab for up to 16 additional doses. Bevacizumab was administered at 15 mg/kg intravenously every three weeks. On this trial, 1,215 patients received at least one bevacizumab dose.

The primary efficacy outcome was investigator-assessed progression-free survival (PFS); overall survival (OS) was a secondary outcome. The estimated median PFS was 18.2 months for patients receiving bevacizumab with chemotherapy followed by single-agent bevacizumab (HR 0.62; 95% CI: 0.52, 0.75; p<0.0001). For those receiving bevacizumab with chemotherapy without single-agent bevacizumab, the estimated median PFS was 12.8 months (HR 0.83; 95% CI: 0.70, 0.98; not significant). For patients receiving chemotherapy without bevacizumab, the estimated median PFS was 12.0 months. Estimated median OS was 43.8 months in the bevacizumab with chemotherapy followed by bevacizumab compared to 40.6 months in the chemotherapy alone arm (HR 0.89; 95% CI: 0.76, 1.05).

Adverse reactions occurring at higher incidence (at least 5%) of patients receiving bevacizumab in GOG-0218 were diarrhea, nausea, stomatitis, fatigue, arthralgia, muscular weakness, pain in extremity, dysarthria, headache, dyspnea, epistaxis, nasal mucosal disorder, and hypertension. Grade 3-4 adverse reactions occurring at a higher incidence (≥2%) in either of the bevacizumab

arms versus the control arm were fatigue, hypertension, platelet count decreased, and white blood cell count decreased.

The recommended bevacizumab dose for stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial surgical resection is 15 mg/kg every 3 weeks with carboplatin and paclitaxel for up to 6 cycles, followed by 15 mg/kg every 3 weeks as a single-agent, for a total of up to 22 cycles.

View full prescribing information for Avastin.

FDA granted bevacizumab orphan product designation for this indication. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System or by calling 1-800-FDA-1088.

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