Generic Name:
Bevacizumab
Trade Name:
Avastin
Company:
Genentech
Notes:

FDA approved bevacizumab 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 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.

A total of 1,873 patients were randomized 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 3 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 (hazard ratio [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 with 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 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, decreased platelet count, and decreased white blood cell count.

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 six cycles, followed by 15 mg/kg every 3 weeks as a single agent, for a total of up to 22 cycles.

Medication Monitor Categories:

Supplemental Approvals
