Avastin® (bevacizumab) – Expanded indication

- On June 13, 2018, Genentech announced the FDA approval of Avastin (bevacizumab), in combination with carboplatin and paclitaxel, followed by Avastin as a single agent, for the treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial surgical resection.

    — Other approved uses for Avastin in ovarian, fallopian tube, and peritoneal cancer include: in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer who received no more than 2 prior chemotherapy regimens; and in combination with carboplatin and paclitaxel, or with carboplatin and gemcitabine, followed by Avastin as a single agent, for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.

- Avastin is also indicated for the treatment of metastatic colorectal cancer; non-squamous non-small cell lung cancer; recurrent glioblastoma; metastatic renal cell carcinoma; and persistent, recurrent, or metastatic cervical cancer.

- In 2018, more than 22,000 women will be diagnosed with ovarian cancer in the U.S. and approximately 14,000 will die from the disease.

    — About 80% of ovarian cancer cases are diagnosed at an advanced stage when the cancer has spread beyond the ovaries.

- The expanded indication for Avastin was based on a placebo-controlled trial in patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer. Patients were randomized to one of three arms: carboplatin plus paclitaxel (CP) followed by placebo alone, CP plus bevacizumab (CPB) followed by placebo alone, or CPB followed by bevacizumab monotherapy (CPBB). The primary endpoint was progression-free survival (PFS).

    — The median PFS was 12 months for the CP arm, 12.8 months for CPB, and 18.2 months for CPBB (HR = 0.62 relative to the CP arm [95% CI: 0.52, 0.75], $p < 0.0001$).
    — The secondary endpoint of overall survival was 40.6 months for the CP arm, 38.8 months for the CPB arm, and 43.8 months for the CPBB arm.

- Avastin carries a boxed warning for gastrointestinal perforations, surgery and wound healing complications, and hemorrhage.

- In patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial surgical resection, the recommended dose is 15 mg/kg intravenously every 3 weeks in combination with carboplatin and paclitaxel for up to 6 cycles, followed by Avastin 15 mg/kg every 3 weeks as a single agent, for a total of up to 22 cycles or until disease progression, whichever occurs earlier.

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- Refer to the Avastin drug label for dosage information in other indications, including platinum-resistant and platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.