Avastin® (bevacizumab) – Expanded Indication

- On December 6, 2016, Genentech announced the FDA approval of Avastin (bevacizumab) injection, in combination with carboplatin and paclitaxel or in combination 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 approved for the treatment of women with platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer in combination with paclitaxel, pegylated liposomal doxorubicin or topotecan chemotherapy.
    - In addition, Avastin is indicated to treat metastatic colorectal cancer; non-squamous non-small cell lung cancer; glioblastoma; metastatic renal cell carcinoma; and persistent, recurrent, or metastatic carcinoma of the cervix.
- Ovarian cancer causes more deaths than any other gynecologic cancer in the U.S. In 2016, an estimated 22,200 women are expected to be diagnosed with ovarian cancer, with about 14,200 deaths occurring from the disease.
    - Patients are said to have 'platinum-sensitive' disease if a relapse occurs six months or longer following the last cycle of platinum-based chemotherapy.
    - About half of those who relapse after initial treatment – over 8,000 women – will have platinum-sensitive ovarian cancer.
- The expanded indication for Avastin was approved based on two clinical trials (GOG-0213, OCEANS) in patients with platinum-sensitive, recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.
    - In GOG-0213, a greater overall survival was achieved with Avastin plus chemotherapy vs. chemotherapy alone (42.6 months vs. 37.3 months; HR = 0.84 [95% CI: 0.69-1.01] and HR = 0.82 [95% CI: 0.68-0.996], depending on stratification factor).
    - In OCEANS, Avastin plus chemotherapy demonstrated significant improvements in progression-free survival vs. placebo plus chemotherapy (12.4 months vs. 8.4 months; HR = 0.46, [95% CI: 0.37-0.58]; p<0.0001). However, overall survival, one of the secondary endpoints in the OCEANS study, was not significantly improved with the addition of Avastin to chemotherapy (HR = 0.95, [95% CI: 0.77-1.17]).
- Avastin carries a boxed warning regarding the risk of gastrointestinal perforations, surgery, and wound healing complications, and hemorrhage.
- The adverse events in the GOG-0213 and OCEANS trials were consistent with those seen in previous trials of Avastin across tumor types for approved indications, but also included fatigue, low white blood cell count with fever, low sodium level in the blood, pain in extremity, low platelet count, too much protein in the urine, high blood pressure and headache.
- For platinum-sensitive patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, the recommend dose of Avastin is 15 mg/kg intravenously (IV) every 3 weeks when administered in combination with carboplatin and paclitaxel for 6 cycles and up to 8 cycles, followed by continued use of Avastin15 mg/kg every 3 weeks as a single agent until disease progression.

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- Alternatively, Avastin may be given 15 mg/kg IV every 3 weeks when administrated in combination with carboplatin and gemcitabine for 6 cycles and up to 10 cycles, followed by continued use of Avastin 15 mg/kg every 3 weeks as a single agent until disease progression.

- Refer to the Avastin drug label for dosing recommendations for the other indications.

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