Presented by Jeannine Brant, PHD, APRN, AOCN, FAAN
Tuesday, March 28, 2017 at 5:30 PM
Seastar Restaurant & Raw Bar
205 108th Ave NE
#100
Bellevue, WA
Please RSVP to Heather Freeborne,
at 425-466-7550 or Freeborne.Heather@Gene.Com or http://www.medforcereg.net/SGEN7473

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Indications
Avastin in combination with paclitaxel, pegylated liposomal doxorubicin or topotecan is indicated 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.
Avastin in combination with paclitaxel and cisplatin or paclitaxel and topotecan is indicated for the treatment of persistent, recurrent, or metastatic carcinoma of the cervix.
Avastin is indicated for the treatment of metastatic renal cell carcinoma in combination with interferon alfa.
Avastin is indicated for the first-line treatment of unresectable, locally advanced, recurrent or metastatic non–squamous non–small cell lung cancer in combination with carboplatin and paclitaxel.
Avastin is indicated for the first- or second-line treatment of patients with metastatic carcinoma of the colon or rectum in combination with intravenous 5-fluorouracil–based chemotherapy.
Avastin, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy, is indicated for the second-line treatment of patients with metastatic colorectal cancer who have progressed on a first-line Avastin-containing regimen. Limitation of Use: Avastin is not indicated for adjuvant treatment of colon cancer.

Boxed WARNINGS
- Gastrointestinal (GI) perforation
  - Serious and sometimes fatal GI perforation occurs at a higher incidence (up to 3.2%) in Avastin-treated patients compared to controls. Discontinue Avastin for GI perforation
- Surgery and wound healing complications
  - The incidence of wound healing and surgical complications, including serious and fatal complications, is increased in Avastin-treated patients
  - Discontinue in patients with wound dehiscence. Discontinue at least 28 days prior to elective surgery. The appropriate interval between termination of Avastin and subsequent elective surgery required to reduce the risks of impaired wound healing/wound dehiscence has not been determined
  - Do not initiate Avastin for at least 28 days after surgery and until the surgical wound is fully healed
- Hemorrhage
  - Severe or fatal hemorrhage, hemoptysis, GI bleeding, CNS hemorrhage, epistaxis, and vaginal bleeding are increased in Avastin-treated patients. Do not administer Avastin to patients with serious hemorrhage or recent hemoptysis

Please see accompanying full Prescribing Information, including Boxed WARNINGS, and next page for additional important safety information.

AVASTIN®
bevacizumab
Injection for intravenous infusion
Boxed WARNINGS

- **Gastrointestinal (GI) perforation**
  - Serious and sometimes fatal GI perforation occurs at a higher incidence in Avastin-treated patients compared to controls.
  - The incidences of GI perforation ranged from 0.3% to 3.2% across clinical studies.
  - Discontinue Avastin in patients with GI perforation.

- **Surgery and wound healing complications**
  - The incidence of wound healing and surgical complications, including serious and fatal complications, is increased in Avastin-treated patients.
  - Do not initiate Avastin for at least 28 days after surgery and until the surgical wound is fully healed. The appropriate interval between termination of Avastin and subsequent elective surgery required to reduce the risks of impaired wound healing/wound dehiscence has not been determined.
  - Discontinue Avastin at least 28 days prior to elective surgery and in patients with wound healing complications requiring medical intervention.

- **Hemorrhage**
  - Severe or fatal hemorrhage, including hemoptysis, GI bleeding, hematemesis, central nervous system hemorrhage, epistaxis, and vaginal bleeding, occurred up to 5-fold more frequently in patients receiving Avastin. Across indications, the incidence of grade 3 hemorrhagic events among patients receiving Avastin ranged from 0.4% to 6.9%.
  - Do not administer Avastin to patients with serious hemorrhage or recent hemoptysis (≥1/2 tsp of red blood).
  - Discontinue Avastin in patients with serious hemorrhage (ie, requiring medical intervention).

Additional serious adverse events

- Additional serious and sometimes fatal adverse events with increased incidence in the Avastin-treated arm vs control included:
  - GI fistulae (up to 2% in metastatic colorectal cancer patients; less commonly in other cancer types).
  - Non-GI fistulae (<1% in trials across various indications; 1.8% in a cervical cancer trial).
  - Arterial thromboembolic events (grade ≥3, 2.6%).
  - Proteinuria (nephrotic syndrome, <1%).

- Additional serious adverse events with increased incidence in the Avastin-treated arm vs control included:
  - GI-vaginal fistulae occurred in 8.3% of patients in a cervical cancer trial.
  - Venous thromboembolism (grade 3–4, up to 10.6%) in patients with persistent, recurrent, or metastatic cervical cancer treated with Avastin.
  - Hypertension (grade 3–4, 5%–18%).
  - Posterior reversible encephalopathy syndrome (PRES) (<0.5%).

- Infusion reactions with the first dose of Avastin were uncommon (<3%), and severe reactions occurred in 0.2% of patients.

- Inform females of reproductive potential of the risk of ovarian failure prior to starting treatment with Avastin.

- Avoid use in patients with ovarian cancer who have evidence of recto-sigmoid involvement by pelvic examination or bowel involvement on CT scan or clinical symptoms of bowel obstruction.

Most common adverse events

- Across indications, the most common adverse reactions observed in Avastin patients at a rate >10% and at least twice the control arm rate were:
  - Epistaxis
  - Headache
  - Hypertension
  - Rhinitis
  - Proteinuria
  - Dry skin
  - Rectal hemorrhage
  - Taste alteration
  - Back pain
  - Exfoliative dermatitis
  - Lacrimation disorder

- Across all studies, Avastin was discontinued in 8.4% to 21% of patients because of adverse reactions.

Pregnancy warning

- Avastin may impair fertility.

- Based on animal data, Avastin may cause fetal harm.

- Advise patients of the potential risk to the fetus during and following Avastin and the need to continue adequate contraception for at least 6 months following the last dose of Avastin.

- For nursing mothers, discontinue nursing or Avastin, taking into account the importance of Avastin to the mother.

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at (888) 835-2555.

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