Mvasi™ (bevacizumab-awwb) – New biosimilar approval

- On September 14, 2017, the FDA approved Mvasi (bevacizumab-awwb), Amgen's biosimilar to Genentech's Avastin® (bevacizumab), for the treatment of multiple types of cancer.
    - Mvasi is the first biosimilar approved in the U.S. for the treatment of cancer.
- Mvasi is indicated for the following:
    - **Metastatic colorectal cancer (MCC):** for first-or second-line treatment of patients with metastatic carcinoma of the colon or rectum in combination with intravenous 5-fluorouracil–based chemotherapy; and in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for the second-line treatment of patients with MCC who have progressed on a first-line bevacizumab product-containing regimen. Mvasi is not indicated for adjuvant treatment of colon cancer
    - **Non-squamous non-small cell lung cancer (NSCLC):** for first-line treatment of unresectable, locally advanced, recurrent or metastatic NSCLC in combination with carboplatin and paclitaxel.
    - **Glioblastoma:** for the treatment of glioblastoma with progressive disease in adult patients following prior therapy as a single agent. The effectiveness of bevacizumab products in glioblastoma is based on an improvement in objective response rate. There are no data demonstrating an improvement in disease-related symptoms or increased survival with bevacizumab products.
    - **Metastatic renal cell carcinoma (mRCC):** for treatment of mRCC in combination with interferon alfa.
    - **Persistent, recurrent, or metastatic carcinoma of the cervix:** in combination with paclitaxel and cisplatin or paclitaxel and topotecan for the treatment of persistent, recurrent, or metastatic carcinoma of the cervix.
- Avastin carries additional indications, for use 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 either 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.
- A biosimilar product is a biological agent that is considered highly similar to an already approved biological drug, known as the reference product. Biological products are generally derived from a living organism and can come from many sources, including humans, animals, microorganisms or yeast.
- A biosimilar product must show no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products.
    - In addition, a biosimilar product may only be approved for the indication(s) and condition(s) that have been FDA approved for the reference product, and must have the same mechanism(s) of action, route(s) of administration, dosage form(s) and strength(s) as the reference product.
    - The facilities where biosimilars are manufactured must also meet the FDA's standards.

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- The approval of Mvasi was based on review of evidence that included extensive structural and functional characterization, animal study data, human pharmacokinetic and pharmacodynamic data, clinical immunogenicity data and other clinical safety and effectiveness data that demonstrates Mvasi is biosimilar to Avastin.

- Mvasi was approved as a biosimilar, ***not*** as an interchangeable product.

- Similar to Avastin, Mvasi carries a boxed warning regarding the risk of gastrointestinal perforations, surgery and wound healing complications, and hemorrhage.

- Other warnings and precautions of Mvasi include gastrointestinal perforations and fistulae, non-gastrointestinal fistulae, arterial thromboembolic events, venous thromboembolic events, hypertension, posterior reversible encephalopathy syndrome, proteinuria, infusion reactions, embryo-fetal toxicity, and ovarian failure.

- The most common adverse reactions (> 10% and at least twice the control arm rate) with Mvasi use were epistaxis, headache, hypertension, rhinitis, proteinuria, taste alteration, dry skin, rectal hemorrhage, lacrimation disorder, back pain, and exfoliative dermatitis.

- The recommended intravenous (IV) dose of Avastin varies by indication.

Indication	Dose
MCC	5 mg/kg or 10 mg/kg every 2 weeks when used in combination with IV 5-fluorouracil-based chemotherapy. Refer to the drug label for the dosing by specific regimen.
MCC	5 mg/kg every 2 weeks or 7.5 mg/kg every 3 weeks when used in combination with a fluoropyrimidine-irinotecan or fluoropyrimidine-oxaliplatin-based chemotherapy regimen in patients who have progressed on a first-line bevacizumab product-containing regimen.
NSCLC	15 mg/kg every 3 weeks in combination with carboplatin and paclitaxel.
Glioblastoma	10 mg/kg every 2 weeks.
mRCC	10 mg/kg every 2 weeks in combination with interferon alfa.
Cervical cancer	15 mg/kg every 3 weeks in combination with one of the following chemotherapy regimens: paclitaxel and cisplatin, or paclitaxel and topotecan.

- The launch plans for Mvasi will depend on pending court decisions. Upon launch, Mvasi will be available as 100 mg/4 mL and 400 mg/16 mL single-dose vials.