Alymsys® (bevacizumab-maly) – New biosimilar approval

- On April 13, 2022, Amneal announced the FDA approval of Alymsys (bevacizumab-maly), biosimilar to Genentech's Avastin® (bevacizumab).
    - Alymsys is the third FDA-approved biosimilar to Avastin. Amgen launched the first biosimilar, Mvasi™ (bevacizumab-awwb) in July 2019, and Pfizer launched Zirabev™ (bevacizumab-bvzr) in January 2020.
- Alymsys, Mvasi, Zirabev and Avastin share the following indications:
    - Metastatic colorectal cancer
    - First-line non-squamous non–small cell lung cancer
    - Recurrent glioblastoma
    - Metastatic renal cell carcinoma
    - Persistent, recurrent, or metastatic cervical cancer, and
    - Epithelial ovarian, fallopian tube, or primary peritoneal cancer.
- The approval of Alymsys is based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Avastin.
- Alymsys has been approved as a biosimilar to Avastin, *not* as an interchangeable product.
- Warnings and precautions of Alymsys include gastrointestinal perforations and fistulae, surgery and wound healing complications, hemorrhage, arterial thromboembolic events, venous thromboembolic events, hypertension, posterior reversible encephalopathy syndrome, renal injury and proteinuria, infusion-related reactions, embryo-fetal toxicity, ovarian failure, and congestive heart failure.
- The most common adverse reactions (> 10%) with Alymsys use were epistaxis, headache, hypertension, rhinitis, proteinuria, taste alteration, dry skin, hemorrhage, lacrimation disorder, back pain and exfoliative dermatitis.
- The recommended dosage of Alymsys varies by indication and patient weight, and is administered by intravenous infusion.
    - Refer to the Alymsys drug label for additional dosing details.
- Amneal's launch plans for Alymsys are pending. Alymsys will be available as 100 mg/4 mL (25 mg/mL) or 400 mg/16 mL (25 mg/mL) single-dose vials.