Vegzelma® (bevacizumab-adcd) – New biosimilar approval

- On September 28, 2022, Celltrion USA announced the FDA approval of Vegzelma (bevacizumab-adcd), biosimilar to Genentech's Avastin® (bevacizumab).
    - Vegzelma is the fourth FDA-approved biosimilar to Avastin.
    - Amgen's Mvasi™ (bevacizumab-awwb) and Pfizer's Zirabev™ (bevacizumab-bvzr) have already launched. Amneal's Alymsys® (bevacizumab-maly) has been approved and is expected to launch sometime in fourth quarter 2022.
- Vegzelma, Avastin, Mvasi, Zirabev and Alymsys 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.
- Avastin is also indicated in combination with Tecentriq® (atezolizumab), for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy.
- The approval of Vegzelma is based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Avastin.
- Vegzelma has been approved as a biosimilar to Avastin, *not as* an interchangeable product.
- Warnings and precautions for Vegzelma 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 Vegzelma use were epistaxis, headache, hypertension, rhinitis, proteinuria, taste alteration, dry skin, hemorrhage, lacrimation disorder, back pain and exfoliative dermatitis.
- The recommended dosage of Vegzelma varies by indication and patient weight, and is administered by intravenous infusion.
    - Refer to the Vegzelma drug label for additional dosing details.
- Celltrion's launch plans for Vegzelma are pending. Vegzelma will be available as single-dose vials containing 100 mg/4 mL (25 mg/mL) or 400 mg/16 mL (25 mg/mL) solution.