

## Avzivi<sup>®</sup> (bevacizumab-tnjn) – New biosimilar approval

- On December 6, 2023, the [FDA approved](#) Bio-Thera/Sandoz's [Avzivi \(bevacizumab-tnjn\)](#), biosimilar to Genentech's [Avastin<sup>®</sup> \(bevacizumab\)](#).
  - Avzivi is the fifth FDA-approved biosimilar to Avastin.
  - Amgen's [Mvasi<sup>™</sup> \(bevacizumab-awwb\)](#), Pfizer's [Zirabev<sup>™</sup> \(bevacizumab-bvzr\)](#), Amneal's [Alymsys<sup>®</sup> \(bevacizumab-maly\)](#) and Celltrion's [Vegzelma<sup>®</sup> \(bevacizumab-adcd\)](#) have already launched.
- Avzivi, 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<sup>®</sup> \(atezolizumab\)](#), for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy.
- The approval of Avzivi is based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Avastin.
- Avzivi has been approved as a biosimilar to Avastin, *not* as an interchangeable product.
- Warnings and precautions for Avzivi 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 Avzivi use were epistaxis, headache, hypertension, rhinitis, proteinuria, taste alteration, dry skin, hemorrhage, lacrimation disorder, back pain and exfoliative dermatitis.
- The recommended dosage of Avzivi varies by indication and patient weight and is administered by intravenous infusion.
  - Refer to the Avzivi drug label for additional dosing details.
- Bio-Thera/Sandoz's launch plans for Avzivi are pending. Avzivi will be available as single-dose vials containing 100 mg/4 mL (25 mg/mL) or 400 mg/16 mL (25 mg/mL) solution.