Fylnetra™ (pegfilgrastim-pbbk) – New biosimilar approval

- On May 27, 2022, Amneal announced the FDA approval of Fylnetra (pegfilgrastim-pbbk), biosimilar to Amgen's Neulasta® (pegfilgrastim).
    - Fylnetra is the fifth FDA-approved biosimilar to Neulasta. Mylan/Biocon launched Fulphila® (pegfilgrastim-jmbd) in July 2018. Coherus launched Udenyca® (pegfilgrastim-cbqv) in January 2019. Sandoz launched Ziextenzo™ (pegfilgrastim-bmez) in November 2019. Pfizer launched Nyvepria™ (pegfilgrastim - apgf) in December 2020.
- Fylnetra, Neulasta, Fulphila, Udenyca, Ziextenzo, and Nyvepria share the following indication:
    - To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.
- Neulasta is also indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation.
- The approval of Fylnetra is based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Neulasta.
- Fylnetra has been approved as a biosimilar to Neulasta, *not as* an interchangeable product.
- Similar to Neulasta, Fulphila, Udenyca, Ziextenzo, and Nyvepria, Fylnetra is contraindicated in patients with a history of serious allergic reactions to human granulocyte colony-stimulating factors such as pegfilgrastim products or filgrastim products.
- Warnings and precautions for Fylnetra include splenic rupture, acute respiratory distress syndrome, serious allergic reactions, use in patients with sickle cell disorders, glomerulonephritis, leukocytosis, thrombocytopenia, capillary leak syndrome, potential for tumor growth stimulatory effects on malignant cells, myelodysplastic syndrome and acute myeloid leukemia in patients with breast and lung cancer, aortitis, and nuclear imaging.
- The most common adverse reactions (≥ 5% difference in incidence vs. placebo) with Fylnetra use were bone pain and pain in extremity.
- The recommended dose of Fylnetra is a single subcutaneous injection of 6 mg administered once per chemotherapy cycle. Dosing in pediatric patients weighing < 45 kg is based on patient weight.
    - Fylnetra should not be administered between 14 days before and 24 hours after administration of cytotoxic chemotherapy.
    - Refer to Fylnetra drug label for additional dosing and administration recommendations.
- Amneal plans to launch Fylnetra sometime in the second half of 2022. Fylnetra will be available as a 6 mg/0.6 mL preservative-free solution in a single-dose prefilled syringe.