Stimufend® (pegfilgrastim-fpgk) – New biosimilar approval

- On September 1, 2022, the FDA approved Fresenius Kabi's Stimufend (pegfilgrastim-fpgk), biosimilar to Amgen's Neulasta® (pegfilgrastim).
    - Stimufend is the sixth FDA-approved biosimilar to Neulasta.
- Stimufend, Neulasta, Fylnetra®, 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 Stimufend is based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Neulasta.
- Stimufend has been approved as a biosimilar to Neulasta, *not as* an interchangeable product.
- Similar to Neulasta, Fulphila, Udenyca, Ziextenzo, Nyvepria, and Fylnetra, Stimufend 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 Stimufend 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 Stimufend use were bone pain and pain in extremity.
- The recommended dose of Stimufend 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.
    - Stimufend should not be administered between 14 days before and 24 hours after administration of cytotoxic chemotherapy.
    - Refer to Stimufend drug label for additional dosing and administration recommendations.
- Fresenius Kabi's launch plans for Stimufend are pending. Stimufend will be available as a 6 mg/0.6 mL preservative-free solution in a single-dose prefilled syringe.