Nyvepria™ (pegfilgrastim-apgf) – New biosimilar approval

- On June 11, 2020, Pfizer announced the FDA approval of Nyvepria (pegfilgrastim-apgf), a biosimilar to Amgen's Neulasta® (pegfilgrastim).
    - Nyvepria is the fourth FDA-approved biosimilar to Neulasta.
    - Mylan/Biocon's Fulphila® (pegfilgrastim-jmbd) was the first biosimilar to Neulasta and was launched in July of 2018. The second biosimilar to Neulasta was Coherus' Udenyca® (pegfilgrastim-cbqv) which launched in January of 2019. The third biosimilar to Neulasta was Sandoz's Ziextenzo™ (pegfilgrastim-bmez) which launched in November 2019.
- Nyvepria, Ziextenzo, Fulphila, Udenyca and Neulasta 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.
    - Nyvepria, Ziextenzo, Fulphila, Udenyca and Neulasta are not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.
- In addition, Neulasta is indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation.
- A biosimilar product is a biological agent that is considered highly similar to an already-approved biological drug, known as the reference product. Biological products are generally derived from a living organism and can come from many sources, including humans, animals, microorganisms or yeast.
    - A biosimilar product must show no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products.
    - In addition, a biosimilar product may only be approved for the indication(s) and condition(s) that have been FDA approved for the reference product, and must have the same mechanism(s) of action, route(s) of administration, dosage form(s) and strength(s) as the reference product.
- Nyvepria has been approved as a biosimilar, ***not*** as an interchangeable product.
- Warnings and precautions of Nyvepria include splenic rupture, acute respiratory distress syndrome, serious allergic reactions, use in patients with sickle cell disorders, glomerulonephritis, leukocytosis, capillary leak syndrome, potential for tumor growth stimulatory effects on malignant cells, aortitis, and nuclear imaging.
- The most common adverse reactions (≥ 5% incidence vs. placebo) with Nyvepria use were bone pain and pain in extremity.
- The recommended dose of Nyvepria is a single subcutaneous injection of 6 mg administered once per chemotherapy cycle.
    - Nyvepria should not be administered between 14 days before and 24 hours after administration of cytotoxic chemotherapy.
    - Refer to the Nyvepria drug label for dosing recommendations for pediatric patients weighing less than 45 kg.

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- Pfizer plans to launch Nyvepria later this year. Nyvepria will be available as a 6 mg/0.6 mL solution in a single-dose prefilled syringe.