Udenyca™ (pegfilgrastim-cbqv) – New biosimilar approval

- On November 2, 2018, Coherus BioSciences announced the FDA approval of Udenyca (pegfilgrastim-cbqv), biosimilar to Amgen's Neulasta® (pegfilgrastim).
    - This is the second FDA-approved biosimilar to Neulasta. The first was Mylan/Biocon's Fulphila™ (pegfilgrastim-jmbd).
- Udenyca, Fulphila, and Neulasta are approved 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.
    - Udenyca, Fulphila, and Neulasta are not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.
- In addition, Neulasta is also 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.
- Udenyca is approved as a biosimilar to Neulasta, ***not*** as an interchangeable product.
- The approval of Udenyca is based on a review of analytical, non-clinical, pharmacokinetic, pharmacodynamic, and immunogenicity studies confirming that Udenyca is highly similar to Neulasta.
- Warnings and precautions of Udenyca 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% difference in incidence vs. placebo) with Udenyca use were bone pain and pain in extremity.
- The recommended dose of Udenyca is a single subcutaneous injection of 6 mg administered once per chemotherapy cycle.
    - Udenyca should not be administered between 14 days before and 24 hours after administration of cytotoxic chemotherapy.
    - For pediatric patients weighing less than 45 kg, weight-based dosing should be used.
    - Refer to the Udenyca drug label for further information.

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- Refer to the Neulasta drug label for the dosing recommendation for the radiation indication.

- Coherus will provide details regarding the pricing and launch of Udenyca during their November 8th earnings call. Udenyca will be available as a 6 mg/0.6 mL single-dose prefilled syringe.

  - Mylan/Biocon launched Fulphila in July 2018.