Fulphila™ (pegfilgrastim-jmdb) – New biosimilar approval

- On June 4, 2018, the FDA announced the approval of Mylan and Biocon's Fulphila (pegfilgrastim-jmdb), 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.
    - Fulphila is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.
- Fulphila is the first FDA-approved biosimilar to Neulasta®.
- 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, the biosimilar product may 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.
    - The facilities where the biosimilars are manufactured must also meet the FDA's standards.
- The approval of Fulphila is based on review of evidence that included extensive structural and functional characterization, animal study data, human pharmacokinetic and pharmacodynamic data, clinical immunogenicity data, and other clinical safety and effectiveness data that demonstrates Fulphila is biosimilar to Neulasta.
- Fulphila has been approved as a biosimilar to Neulasta, ***not*** as an interchangeable product.
- Fulphila is contraindicated in patients with a history of serious allergic reactions to pegfilgrastim products or filgrastim products. Reactions have included anaphylaxis.
- Warnings and precautions of Fulphila include splenic rupture, acute respiratory distress syndrome, serious allergic reactions, use in patients with sickle cell disorders, glomerulonephritis, leukocytosis, capillary leak syndrome, and potential for tumor growth stimulatory effects on malignant cells.
- The most common adverse reactions (≥ 5% difference in incidence compared to placebo) with pegfilgrastim use were bone pain and pain in extremity.
- The recommended dose of Fulphila is a single subcutaneous injection of 6 mg administered once per chemotherapy cycle.
    - Fulphila 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 Fulphila drug label for additional information.

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- Mylan and Biocon plan to launch Fulphila in the coming weeks. Fulphila will be available as a dispensing pack containing one 6 mg/0.6 mL prefilled single-dose syringe and a 29 gauge, ½ inch needle with an UltraSafe Passive Plus™ Needle Guard.