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USFDA approves Mylan and Biocon's Fulphila

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Fulphila is expected to be the first biosimilar pegfilgrastim available in the U.S. to help patients with nonmyeloid cancers reduce the risk of infection following myelosuppressive chemotherapy.

Mylan N.V. and Biocon Ltd. have announced that the U.S. Food and Drug Administration (FDA) has approved Mylan's Fulphila (pegfilgrastim-jmbd), a biosimilar to Neulasta (pegfilgrastim), co-developed with Biocon. Fulphila has been approved to reduce the duration of febrile neutropenia (fever or other signs of infection with a low count of neutrophils, a type of white blood cells) in patients treated with chemotherapy in certain types of cancer.

Fulphila is the first FDA-approved biosimilar to Neulasta and the second biosimilar from Mylan and Biocon's joint portfolio approved in the U.S. Mylan anticipates launching Fulphila in the coming weeks, representing the first alternative, more affordable treatment option to Neulasta for oncology patients. A suite of patient services also will be available at launch to further support patients and caregivers with treatment.

Mylan CEO Heather Bresch commented: "I couldn't be prouder of this approval for Fulphila, the first alternative option for pegfilgrastim approved in the U.S., as it represents an important milestone for patients and further demonstrates Mylan's continued fight to expand access to medicine. FDA's approval of this product, as well as the agency's continued focus on biosimilars, mark crucial steps towards lowering treatment costs and providing alternative options for patients. As a leading supplier of cancer medicines in the U.S, Mylan is committed to offering affordable and accessible solutions for patients with cancer at every step of their journey. Enhancing access to treatment has always been our top priority and what we'll continue to deliver to the healthcare system in the U.S. and beyond."

Mylan President Rajiv Malik added: "Today's approval of Fulphila represents a meaningful step forward in the affordability and accessibility of cancer care in the U.S. It also is yet another confirmation of Mylan's deep scientific, clinical, regulatory and intellectual property capabilities, which are widely recognized in the industry and bolster Mylan's reputationas a partner

of choice in the global effort to bring complex medicines to market. The approval of Fulphila, the first biosimilar to Neulasta, joins other recent examples such as the approval of Ogivri, the first biosimilar to Herceptin, in the growing portfolio of complex medicines that Mylan is making available for patients who need them. We're pleased to reach this important milestone in partnership with Biocon and proud of the progress of our biosimilars program. We look forward to launching Fulphila and continuing to increase access to more affordable treatments."

As a global leader in the development and manufacturing of complex products, Mylan has a portfolio of 20 biosimilar and insulin analog products – one of the industry's largest and most diverse portfolios – and deep experience with more than 60 marketing authorizations for biosimilar products worldwide.

Mylan was the first company to receive FDA approval of Ogivri, a biosimilar to Herceptin(trastuzumab), in late 2017 and has continued to obtain regulatory approvals for biosimilar trastuzumab in nearly 30 additional countries around the world.

Biocon CEO & Joint Managing Director, Dr. Arun Chandavarkar, said: "It's a moment of great pride to be the first to receive approval for a biosimilar pegfilgrastim by the USFDA. This important milestone comes soon after our achievement of being the first to receive USFDA approval for biosimilar trastuzumab. It represents a further endorsement of the Biocon-Mylan partnership's ability to successfully develop complex molecules to exacting quality and regulatory standards. This approval expands our oncology portfolio for the benefit of cancer patients and supports our mission to improve access to high quality, affordable biopharmaceuticals globally."

The approval for Fulphila was based on a comprehensive package of analytical, nonclinical and clinical data, which confirmed that the product is highly similar to Neulasta. The data demonstrated that there were no clinically meaningful differences between the biosimilar product and Neulasta in terms of safety, purity and potency.

Neulasta had U.S. sales of $4.2 billion for the 12 months ending March 31, 2018, according to IQVIA.

Fulphila is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. Do not administer Fulphila to patients with a history of serious allergic reactions to pegfilgrastim or filgrastim. Splenic rupture and sickle cell crisis, including fatal cases, can occur following the administration of Fulphila. DiscontinueFulphila in patients with Acute Respiratory Distress Syndrome and consider dose reduction or interruption in patients with glomerulonephritis. The most common adverse reactions are bone pain and pain in extremity.

Ogivri is approved for the treatment of HER2-overexpressing breast cancer and metastatic stomach cancer (gastric or gastroesophageal junction adenocarcinoma). It may cause cardiomyopathy, infusion reactions, embryo-fetal toxicity and pulmonary toxicity.

- Cardiomyopathy: Ogivri can result in subclinical and clinical cardiac failure manifesting as CHF, and decreased LVEF, with greatest risk when administered concurrently with anthracyclines. Evaluate cardiac function prior to and during treatment. Discontinue Herceptin for cardiomyopathy.
- Infusion Reactions, Pulmonary Toxicity: Discontinue Herceptin for anaphylaxis, angioedema, interstitial pneumonitis, or acute respiratory distress syndrome.
- Embryo-Fetal Toxicity: Exposure to Herceptin during pregnancy can result in oligohydramnios, in some cases complicated by pulmonary hypoplasia and neonatal death. Advise patients of these risks and the need for effective contraception.

Bringing Access to Biologics

Biologic drugs, like Neulasta, represent a large and increasing portion of the overall prescription drug market. They are important in the treatment of many chronic and acute diseases, including cancer. However, these drugs can cost far more than traditional prescription drugs, and their cost can prohibit access. According to a survey from the American Society for Clinical Oncology, more than half (56%) of respondents said they were very or somewhat concerned they could afford treatment. Biologics accounted for 70% of drug spending growth between 2010 and 2015.

Biosimilar medicines are deemed by FDA to be highly similar to an already-approved biologic product. They fill an urgent and unmet need for more affordable alternatives to biologic therapies, increasing access and providing savings for patients and the overall healthcare system. It is projected that biosimilars will generate a savings of $54 billion in direct spending on biologic drugs in the U.S. between 2017 and 2026.