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Biocon and Mylan launches biosimilar Fulphila in Canada

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Fulphila is approved by Health Canada to decrease the incidence of infection



Biocon and Mylan has announced the launch of Fulphila®, a biosimilar to Neulasta® (pegfilgrastim).

Fulphila is approved by Health Canada to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-neoplastic drugs.

The approval of Fulphila was based on a comprehensive package of analytical, nonclinical and clinical data, which confirmed that the product is highly similar to Neulasta and no clinically meaningful differences in terms of safety and efficacy exist.

Dr Christiane Hamacher, CEO, Biocon Biologics, CEO said, “We are pleased to expand access to our high quality biosimilar pegfilgrastim to patients in Canada, after a successful launch in the US. This is the second biosimilar from our portfolio to be launched in Canada by our partner Mylan and is an endorsement of our science, development and manufacturing capabilities in the area of biologics. We are committed to serve 5 million patients through our biosimilars portfolio and cross a revenue milestone of US$1bn by FY22.”

David Simpson, Country Manager, Mylan Canada commented, “As a global leader in the development of complex products, including biosimilar medicines, Mylan is proud to launch Fulphila in Canada. We have reached a negotiated agreement with the Pan-Canadian Pharmaceutical Alliance (pCPA) to help expand access to treatment and reduce costs for cancer patients. Fulphila is the second biosimilar to be offered by Mylan through the Mylan-Biocon Biologics partnership in Canada and the second biosimilar approved by Health Canada through this collaboration to support cancer patients. With Mylan’s global portfolio of 20 biosimilar and insulin analog products in development or on the market, we are bringing vast biosimilars experience to the market here in Canada. Among these products is an extensive oncology portfolio increasing choice and access for patients across the region.”

A suite of patient services will be available at launch to further support patients and caregivers with treatment.

Mylan and Biocon Biologics are exclusive partners on a broad portfolio of biosimilar and insulin products. Biosimilar pegfilgrastim is one of the 11 biologic products being co-developed by Mylan and Biocon for the global marketplace. Mylan has exclusive commercialization rights for the product in the U.S., Canada, Japan, Australia, New Zealand and in the European Union and European Free Trade Association countries. Biocon has shared or co-exclusive commercialization rights with Mylan for the product in the rest of the world.