Company Statement

November 30, 2018

Biosimilar Pegfilgrastim Co-Developed by Biocon Receives Approval in EU

Fulphila®, a biosimilar Pegfilgrastim jointly developed by Biocon and Mylan, has been approved in EU. The European Commission has granted Marketing Authorization for Fulphila® to our partner Mylan.

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) had issued a positive opinion recommending approval of Fulphila® as a biosimilar to Amgen's Neulasta®, which is indicated for the reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy, in September 2018.

Biosimilar Pegfilgrastim treatment can be used to stimulate bone marrow to produce more neutrophils to fight infection in patients undergoing chemotherapy."

- Company Spokesperson

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