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Biocon and Mylan launch Fulphila

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Fulphila is now available on the Pharmaceutical Benefits Scheme (PBS)



Biocon and Mylan has announced the launch of Fulphila®, a biosimilar to Neulasta® (pegfilgrastim) in Australia. Fulphila is approved by the Therapeutic Goods Administration for the treatment of cancer patients following chemotherapy, to decrease the duration of severe neutropenia and so reduce the incidence of infections, as manifested by febrile neutropenia.

Fulphila is now available on the Pharmaceutical Benefits Scheme (PBS).

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 said, “We are extremely pleased to enable access to our high quality, affordable biosimilar pegfilgrastim for patients in Australia. Fulphila, co-developed by Biocon Biologics and Mylan, is the third biosimilar to be commercialized in Australia and we hope that continued penetration of our biosimilars will enable higher cost savings for the Australian healthcare system. We are committed to use our science, scale and expertise to shift the access paradigm for patients in need of biosimilars like pegfilgrastim across the globe.”

Mylan Australia Country Manager, Sylvain Vigneault, commented, “Mylan is proud to launch Fulphila, the third biosimilar to be offered through the Mylan-Biocon Biologics partnership in Australia, as part of its commitment to expand access to more affordable medicines. Biosimilars ensure patients have timely and affordable access to quality, safe and effective treatments in a way that is sustainable for the Pharmaceutical Benefits Scheme. Globally, Mylan is a leader in biosimilars with one of the largest and most diverse biosimilars portfolios which includes 20 biosimilar and insulin analog products in development or on the market. We’re pleased to continue to bring this experience and expertise to patients in Australia.”

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

Fulphila, co-developed by Biocon Biologics and Mylan, was the first biosimilar pegfilgrastim to be approved in the U.S. and was successfully launched in July 2018, thus expanding access for patients in need of an affordable alternative. Fulphila has received regulatory approval in more than 30 countries around the world.

More affordable treatment options such as biosimilars for healthcare providers and their patients enable savings for healthcare systems around the world, including the PBS in Australia.

The Australian government recognises the importance of driving biosimilar uptake to create a competitive and sustainable biosimilars market. In 2015, they committed to the Biosimilar Awareness Initiative and in 2018 they increased their commitment by supporting the Generic and Biosimilar Medicines Association through a $5 million grant to undertake not only increased education around biosimilars in general, but also activities that further promote the appropriate prescribing, dispensing and use of biosimilar medicines.

Biocon Biologics’ scientific expertise and world-class R&D and manufacturing facilities have enabled it to bring multiple biosimilar therapeutics to the US and Europe. It has a product pipeline of 28 molecules, including 11 with Mylan, several with Sandoz, and is developing many independently. The Company’s therapeutic basket includes molecules from diabetes, oncology, immunology, dermatology, ophthalmology, neurology, rheumatology and inflammatory diseases.

Mylan and Biocon Biologics are exclusive partners on a broad portfolio of biosimilar and insulin products. Our 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 co-exclusive commercialization rights with Mylan for the product in the rest of the world.