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Biocon, Mylan announce positive CHMP opinion for Fulphila

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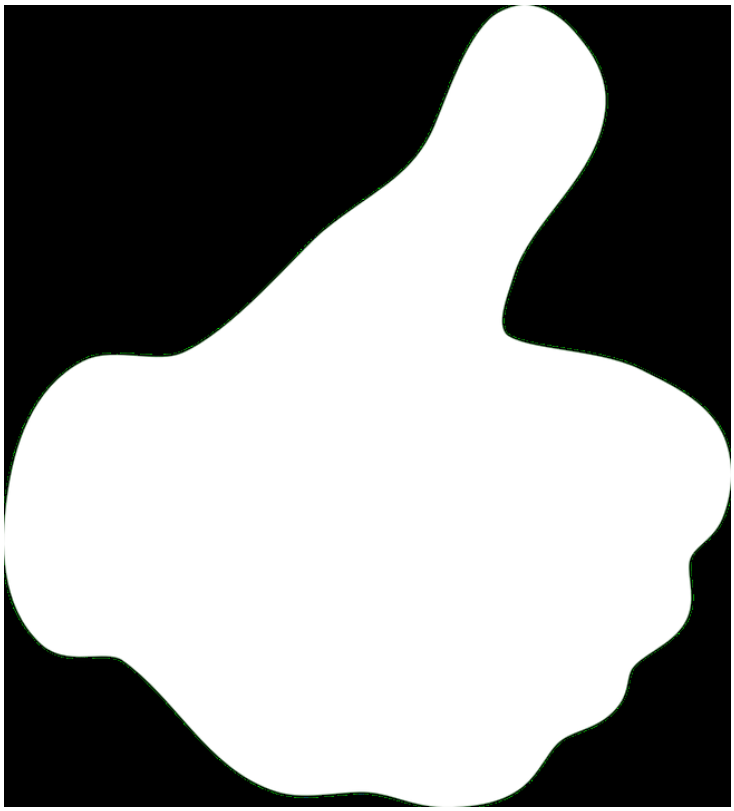
Fulphila is a biosimilar to Amgen's Neulasta (pegfilgrastim).



Biocon Ltd. and Mylan N.V. has announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending approval of Fulphila, a biosimilar to Amgen’s Neulasta (pegfilgrastim).

The CHMP positive opinion is based upon a review of evidence demonstrating biosimilarity. Data submitted as part of the Marketing Authorization Application included similarity assessment in analytical testing, preclinical and clinical studies that demonstrated biosimilarity to the reference product, Neulasta. The Phase I program in healthy volunteers and Phase III clinical study conducted in breast cancer patients receiving adjuvant and neoadjuvant chemotherapy, demonstrated no clinically meaningful differences in terms of pharmacokinetics, pharmacodynamics, safety, efficacy and immunogenicity compared to Neulasta.

The CHMP positive opinion will now be considered by the European Commission. The decision on approval is expected by November 2018.

Fulphila was approved by the U.S. Food and Drug Administration (FDA) earlier this year and is the first FDA-approved

biosimilar for Neulasta in the U.S. Regulatory applications for Fulphila also have been submitted in Australia, New Zealand, Canada and several other countries.

Biocon CEO & Joint Managing Director, Dr. Arun Chandavarkar, said: "CHMP's decision to recommend approval of Biocon and Mylan's biosimilar Pegfilgrastim brings us a step closer to offer this high quality, affordable biologic therapy for cancer patients in the EU, having launched this product in the US, earlier this year. It is an outcome of our commitment to enhance access for patients and be a leading global biosimilars player on the back of significant investments in R&D and global scale manufacturing, together with our partner Mylan."

Mylan President Rajiv Malik commented: "We are very proud to be a leader in bringing the first wave of biosimilars to the European market and driving greater access to more affordable treatment options for patients living with chronic and life-threatening illness such as cancer. Receiving CHMP positive opinion for our pegfilgrastim biosimilar, Fulphila, is a key milestone in this journey, demonstrating our commitment to patient and healthcare communities across Europe and the strength of our collaboration with Biocon."