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## Biocon, Mylan announce positive CHMP opinion for Fulphila

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 programme 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.