Mylan
Better Health
for a Better World

Rafael Muniz M.D., Head, Global Medical Affairs
Abhijit Barve M.D. Ph.D., Head, Global Clinical Research

Mylan
1000 Mylan Boulevard
Canonsburg, PA 15317

Phone: 412-514-9644
Email: rafael.muniz@mylan.com
abhijit.barve@mylan.com

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NCCN Guidelines Panel: Myeloid Growth Factors

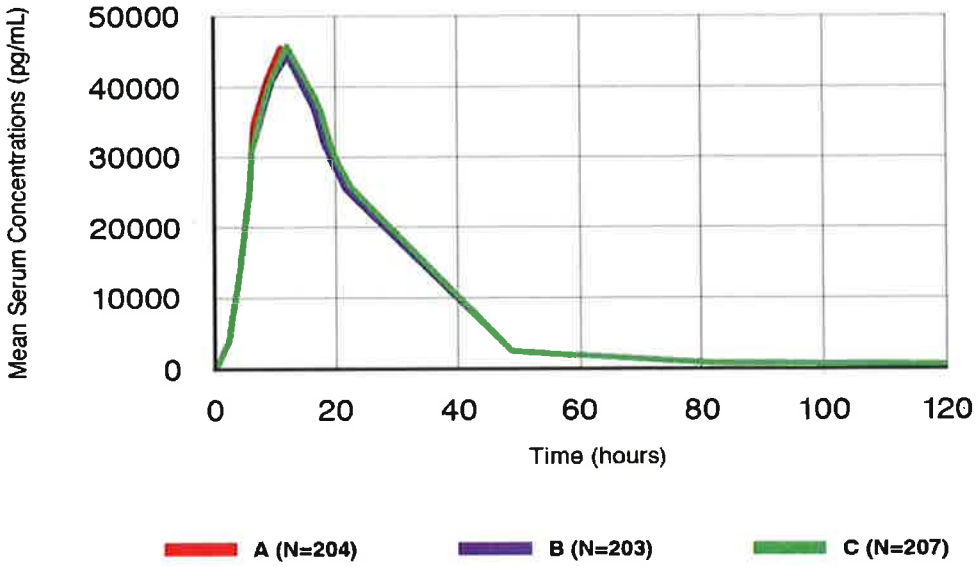
Dear Panel Members,

On behalf of Mylan, we respectfully request the NCCN Myeloid Growth Factors Panel to review the enclosed data for inclusion of the leukocyte growth factor Biosimilar Pegfilgrastim-JMDB (Fulphila®) indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

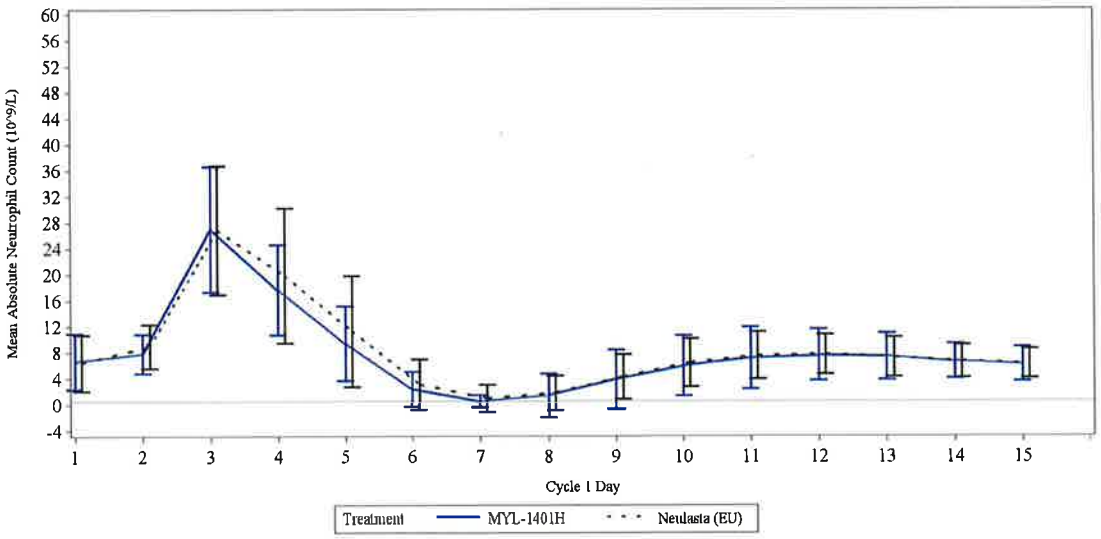
Rationale: The FDA approved Pegfilgrastim-JMDB on June 4,2018 after satisfying the requirements as a Biosimilar to Pegfilgrastim (Neulasta®). Based on the totality of evidence, including from studies assessing preclinical characterization (Waller et al 2018), pharmacokinetics and pharmacodynamics (Waller et al 2018),i clinical safety and effectiveness (Waller et al 2016), and immunogenicity (Waller et al 2017), Fulphila was demonstrated to be highly similar to the reference product, Neulasta® .

Since it's approval, Fulphila has provided a lower cost alternative to the reference product and has been embraced by Oncologists and patients alike. In the US, only 2% of the US population uses biologics, but they account for 26% of prescription drug spending. There is an urgent, unmet need to provide more affordable treatment options for patients through the availability of biosimilars.

To Date, approximately 30% of Payor Organizations across the US have approved Pegfilgrastim-JMDB onto their formularies with many more pending reviews.



A = MYL-1401H; B = EU-Neulasta; C = US-Neulasta



Mean ± SD Absolute Neutrophil Count Over Time by Treatment (PP Population)

The following references are submitted in support of this proposed change.

1) Waller CF, Tiessen RG, Lawrence TE, et al. A pharmacokinetic and pharmacodynamic equivalence trial of the proposed pegfilgrastim biosimilar, MYL-1410H, versus reference pegfilgrastim. J Cancer Res Clin Oncol. 2018;144(6):1087-1095.

2) Waller C, Blakeley C, Pennella E, et al. Phase 3 efficacy and safety trial of proposed pegfilgrastim biosimilar MYL-1401H vs EU-Neulasta® in the prophylaxis of chemotherapy-induced neutropenia [Oral Presentation]. Presented at the European Society of Medical Oncology 2016 Congress; October 7-11, 2016; Copenhagen, Denmark.

3) Waller CF, Ranganna GM, Pennella EJ, et al. Comparison of immunogenicity between the proposed pegfilgrastim biosimilar MYL-1401H and reference pegfilgrastim [Poster]. Presented at the 59th American Society of Hematology Annual Meeting & Exposition; December 9-12, 2017; Atlanta, GA.
4) Fulphila™ (pegfilgrastim-jmbd) injection prescribing information. Mylan GmbHC, Zurich, Switzerland. June 2018.
5) FDA. Scientific considerations in demonstrating biosimilarity to a reference product: guidance for industry. Available at: https://www.fda.gov/downloads/drugs/guidances/ucm291128.pdf. Accessed on 4/16/2018.

We sincerely appreciate your consideration of our request.

Thank You

Rafael Muniz M.D.
Head, Global Medical Affairs
Mylan

Abhijit Barve M.D., Ph.D.
Head, Global Clinical Research
Mylan