FAQs: Tbo-filgrastim

**What is a biosimilar?**
A biosimilar is a biological product very similar to a reference biological product. Biosimilars are not completely identical to the reference product because of the complex structure of biologics and the intricate synthesis process during manufacturing.

For a product to be considered “biosimilar,” FDA requires minimal differences in inactive components and no clinically meaningful differences in safety, purity, and potency to the reference product. FDA will evaluate biosimilar interchangeability to a reference product on case-by-case basis. No information is available for tbo-filgrastim and filgrastim interchangeability.

**What are the differences between the biosimilar pathway and the way FDA approves generic drugs?**
FDA’s new biosimilar pathway is a more demanding process than the traditional generic drug pathway uses for small drug molecules. The biosimilar pathway takes into consideration the complex nature of biological drugs. This new pathway requires extensive analysis on biosimilar structure and functional characterization, immunogenicity studies, as well as new safety and efficacy data from clinical trials.

**Is tbo-filgrastim a biosimilar?**
No, there are currently no biosimilars available in the United States (U.S). Tbo-filgrastim is not a biosimilar. Teva submitted a full Biologics License Application (BLA) for tbo-filgrastim prior to the creation of FDA’s new biosimilar pathway. Tbo-filgrastim was filed under the biosimilar pathway in Europe and is marketed there as a biosimilar product called Tevagrastim®.

**How similar are the molecular characteristics of filgrastim and tbo-filgrastim?**
Although separately licensed biologics, both filgrastim and tbo-filgrastim are non-glycosylated versions of recombinant methionyl human granulocyte colony-stimulating growth factor (G-CSF). They have the same protein length (175 amino acids), the same molecular weight (18,800 daltons), and are both derived from *E. coli* expression systems.

**Does tbo-filgrastim have the same indications as filgrastim?**
No, tbo-filgrastim and filgrastim have different indications. Tbo-filgrastim is indicated to shorten the duration of chemotherapy-induced severe neutropenia in patients with nonmyeloid cancers. Filgrastim has 5 indications including the reduction of infection associated with chemotherapy-induced febrile neutropenia in patients with nonmyeloid cancer.

**Were there new clinical trials for tbo-filgrastim?**
Yes, 3 new, Phase III clinical trials evaluated the efficacy of tbo-filgrastim. The pivotal trial compared tbo-filgrastim with a European filgrastim product and placebo in patients with breast cancer. There are 2 other randomized controlled trials comparing tbo-filgrastim with a European filgrastim product in patients with lung cancer or non-Hodgkin lymphoma.

**Are the doses the same for tbo-filgrastim and filgrastim?**
Yes, tbo-filgrastim and filgrastim have the same dosing. Both products are dosed as 0.5 mcg/kg once daily and are available as 300 mcg/0.5 mL and 480 mcg/0.8 mL prefilled, single-use syringes. Filgrastim is also available in vials and can be administered by subcutaneous and intravenous routes. Tbo-filgrastim is only available as a prefilled syringe and is labeled for subcutaneous administration only.
Can tbo-filgrastim be interchanged with filgrastim?
It depends on the clinical setting and institution. In the outpatient setting, tbo-filgrastim cannot be automatically interchanged with filgrastim without a new prescription. In the inpatient setting, an institution specific therapeutic interchange could allow for automatic interchange.

Why was “tbo” used in front of tbo-filgrastim for naming?
“Tbo” is used in front of filgrastim to distinguish it from the reference biological product, filgrastim (Neupogen®). Originally FDA accepted the proposed name, Neutroval, for tbo-filgrastim, but later rescinded approval due to confusion between similar-sounding names Neupogen®, Neulasta®, and Neumega®.

FDA would like to be able to clearly differentiate between similar biological entities for safety and tracking purposes, however, it is unclear if biosimilar products in the future will require a prefix.

What precautions should be taken to avoid confusing tbo-filgrastim and filgrastim?
Medication errors related to name confusion between tbo-filgrastim and filgrastim are possible. To avoid name confusion between tbo-filgrastim and filgrastim, please consider the following:

- Use both the FDA-approved brand (Neupogen®) and non-proprietary (filgrastim) names when ordering filgrastim. Include both names when communicating medication orders and on preprinted order sets and computerized provider order entry (CPOE) systems.
- Educate providers of the potential for name confusion within CPOE and electronic compendia information.

What is the cost difference between tbo-filgrastim and filgrastim?
Pricing information for tbo-filgrastim is not currently available. It is unclear at this time how payor reimbursement policies and purchasing contracts will be impacted by tbo-filgrastim availability. However, as a separately licensed biologic, tbo-filgrastim will have a unique “J” code distinct from filgrastim.

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