Pfizer Logo

U.S. FDA Approves Pfizer's Biosimilar NIVESTYM™ (filgrastim-aafi)

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NIVESTYM™, a biosimilar to Neupogen ® (filgrastim), is Pfizer's fourth biosimilar to be approved by the FDA

Pfizer Inc. (NYSE:PFE) today announced that the United States (U.S.) Food and Drug Administration (FDA) has approved NIVESTYM™ (filgrastim-aafi), a biosimilar to Neupogen[1] (filgrastim), for all eligible indications of the reference product.

"The FDA approval of NIVESTYM marks an important step in helping expand access to critical treatment options for patients with neutropenia, many of whom have cancer and can be hospitalized for potentially life-threatening side effects stemming from chemotherapy," said Berk Gurdogan, U.S. Institutions President, Pfizer Essential Health. "We believe biosimilars, like NIVESTYM, are essential in helping to address evolving healthcare needs and may provide more affordable medicines to patients."

The FDA approval was based on a review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity of NIVESTYM compared to its reference product.

In the U.S., NIVESTYM is indicated:[2]

- To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.
- For reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML).
- To reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT).
- For the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.
- For chronic administration to reduce the incidence and duration of sequelae of severe neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

NIVESTYM is expected to be available in the U.S. at a significant discount to the current wholesale acquisition cost (WAC) of Neupogen. WAC is not inclusive of discounts to payers, providers, distributors and other purchasing organizations.

NIVESTYM is Pfizer's fourth biosimilar to be approved by the U.S. FDA. Pfizer's biosimilars pipeline consists of 10 distinct biosimilar molecules with five assets in mid-to-late stage clinical development.[3]

NIVESTYM™ IMPORTANT SAFETY INFORMATION

Do not take NIVESTYM if you have had a serious allergic reaction to human G-CSFs such as filgrastim or pegfilgrastim products.

Before you take NIVESTYM, tell your healthcare provider all about your medical conditions, including if you:

- have a sickle cell disorder
- have kidney problems
- are receiving radiation therapy
- are pregnant or plan to become pregnant. It is not known if NIVESTYM will harm your unborn baby
- are breastfeeding or plan to breastfeed. It is not known if NIVESTYM passes into your breast milk

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive NIVESTYM?

- NIVESTYM injections can be given by a healthcare provider by intravenous (IV) infusion or under your skin (subcutaneous injection). Your healthcare provider may decide that subcutaneous injections can be given at home by you or your caregiver. If NIVESTYM is given at home, see the detailed "Instructions for Use" that comes with your NIVESTYM prescription for information on how to prepare and inject a dose of NIVESTYM.
- You and your caregiver should be shown how to prepare and inject NIVESTYM, before you use it, by your healthcare provider.
- Your healthcare provider will tell you how much NIVESTYM to inject and when to inject it. Do not change your dose or stop NIVESTYM unless your healthcare provider tells you to.
- If you are receiving NIVESTYM because you are also receiving chemotherapy, your dose of NIVESTYM should be injected at least 24 hours before or 24 hours after your dose of chemotherapy.
- If you miss a dose of NIVESTYM, talk to your healthcare provider about when you should give your next dose.

What are the most common side effects of NIVESTYM?

- The most common side effects of NIVESTYM include aching in the bones and muscles.

What are possible side effects of NIVESTYM?

NIVESTYM may cause serious side effects including:

- **Spleen rupture.** Your spleen may become enlarged and can rupture. A ruptured spleen can cause death.
- **Acute Respiratory Distress Syndrome (ARDS).** ARDS is a serious lung problem.
- **Serious allergic reactions.** These can occur anywhere in your body. If you have an allergic reaction, stop using NIVESTYM.
- **Sickle cell crises.** Serious sickle cell crises have happened in people with sickle cell disorders receiving NIVESTYM that have sometimes led to death.
- **Kidney injury (glomerulonephritis).** NIVESTYM can cause kidney injury.
- **Capillary Leak Syndrome.** NIVESTYM can cause fluid to leak from blood vessels into your body's tissues. This condition is called "Capillary Leak Syndrome" (CLS). CLS can quickly cause you to have symptoms that may become life-threatening.

- **Decreased platelet count (thrombocytopenia).** Your healthcare provider will check your blood during treatment with NIVESTYM. Tell your healthcare provider if you have unusual bleeding or bruising during treatment with NIVESTYM. This could be a sign of decreased platelet counts, which may reduce the ability of your blood to clot.
- **Increased white blood cell count (leukocytosis).** Your healthcare provider will check your blood during treatment with NIVESTYM.
- **Inflammation of your blood vessels (cutaneous vasculitis).** Tell your healthcare provider if you develop purple spots or redness of your skin.

Call your healthcare provider or seek emergency medical help right away if you have:

- pain in the left upper stomach area or left shoulder
- symptoms of sickle cell crisis such as pain or trouble breathing
- shortness of breath, with or without a fever, any trouble breathing, wheezing or a fast rate of breathing
- a rash over your whole body, swelling around your mouth or eyes, fast heart rate and sweating
- swelling or puffiness, especially swelling of your stomach-area and feeling of fullness
- swelling of your face and ankles
- blood in your urine or dark colored urine
- less than usual urination
- dizziness or are feeling faint
- a general feeling of tiredness

These are not all the possible side effects of NIVESTYM. Call your healthcare provider for medical advice about side effects.

You are encouraged to report adverse events related to Pfizer products by calling 1-800-438-1985 (U.S. only). If you prefer, you may contact the U.S. Food and Drug Administration (FDA) directly. Visit http://www.fda.gov/MedWatch or call 1-800-FDA-1088.

Please see full Prescribing Information and Patient Information for NIVESTYM (filgrastim-aafi).

Working together for a healthier world®

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and follow us on Twitter at @Pfizer and @Pfizer_News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

DISCLOSURE NOTICE: The information contained in this release is as of July 20, 2018. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about NIVESTYM™ (filgrastim-aafi), including its potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the launch timing and commercial success of NIVESTYM in the United States; the uncertainties inherent in research and development; whether and when any applications for NIVESTYM may be filed with regulatory authorities in any other jurisdictions; whether and when regulatory authorities in any other jurisdictions may approve any such other applications that are pending or that may be filed for NIVESTYM, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted and, if approved, whether NIVESTYM will be commercially successful; intellectual property and/or litigation implications; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of NIVESTYM; uncertainties regarding access challenges for our biosimilar products where our product may not receive access at parity to the innovator product and remains in a disadvantaged position; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 10-Q and Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

[1] Neupogen® is a registered trademark of Amgen Inc.
[2] Nivestym™ (filgrastim-aafi) Prescribing Information. New York. NY: Pfizer Inc: 2018. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/761080s000lbl.pdf?utm_campaign=FDA%20approves%20
aafi%29%20a%20biosimilar%20to%20Neupogen%20%28filgrastim%29&utm_medium=email&utm_source=Eloqua
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[3] Pfizer. (2018, January 30). Pfizer pipeline. Retrieved from https://www.pfizer.com/sites/default/files/product-pipeline/01302018_PipelineUpdate.pdf.



Pfizer Inc. Media: Thomas Biegi, +1 212-733-2204 Thomas.Biegi@pfizer.com or Investors: Ryan Crowe, +1 212-733-8160 Ryan.Crowe@pfizer.com