

# Fresenius Kabi launches biosimilar Stimufend® (pegfilgrastim-fpgk) in the U.S.

**February 16, 2023**

- Fresenius Kabi's first U.S. biosimilar launch
- Provides accessible, high-quality treatment option for U.S. cancer patients undergoing chemotherapy to reduce the incidence of infection as manifested by febrile neutropenia
- Strengthens Fresenius Kabi's heritage in oncology and its commitment to oncology patients
- The expansion of the company's global biosimilars portfolio focused on oncology and immunology is a significant key milestone in the company's Vision 2026 growth strategy



Fresenius Kabi, a global health care company that specializes in pharmaceuticals, medical technologies, and nutrition products for critical and chronic conditions, announced today the launch of its pegfilgrastim biosimilar, Stimufend® (pegfilgrastim-fpgk), in the United States (U.S.).

Stimufend® was approved by the United States (U.S.) Food and Drug Administration (FDA) in September 2022 for use in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Stimufend® is commercially available in a 6 mg/0.6 mL solution in a single-dose pre-filled syringe combined with a passive needle guard.

“Fresenius Kabi’s first biosimilars launch in the U.S. is a proud moment and a significant key milestone for us and our Vision 2026. We are expanding into a highly important and fast-growing market for biopharmaceuticals and Stimufend® is the first of our biosimilars portfolio to support cancer patients in the U.S. Stimufend® offers healthcare providers a high-quality treatment alternative while contributing to a sustainable healthcare system in the U.S.,” said Michael Sen, CEO of Fresenius, and acting CEO of Fresenius Kabi.

“We are excited to provide this supportive care option to U.S. patients and physicians via our dedicated U.S. biosimilars organization. This launch is a testimonial of our heritage in oncology and our commitment to oncology patients across the world”, said Dr. Michael Schönhofen, Fresenius Kabi’s Chief Operating Officer and Member of the Fresenius Kabi Management Board.

In October 2022, the company launched its pegfilgrastim biosimilar in a prefilled syringe in France, following the European Commission’s (EC) marketing authorization granted in March 2022.

### **About Stimufend®, a pegfilgrastim biosimilar**

Stimufend® (pegfilgrastim-fpgk), a pegfilgrastim biosimilar medicine of Neulasta®\*\*, is a leukocyte growth factor 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.\*\*\*

Stimufend® is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

\* Stimufend® (pegfilgrastim-fpgk) is a registered trademark of Fresenius Kabi Deutschland GmbH in selected countries.

\*\* Neulasta® is a registered trademark of Amgen Inc.

\*\*\* Pegfilgrastim is a long-acting form of filgrastim (recombinant human granulocyte colony-stimulating factor or G-CSF) which serves to stimulate the production of white blood cells (neutrophils).

For more information about biosimilars, please visit <https://biosimilars.fresenius-kabi.com>.

For more information about biosimilars in the U.S., please visit [\*\*Biosimilars - Fresenius Kabi USA \(fresenius-kabi.com\)\*\*](https://www.fresenius-kabi.com/biosimilars).

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Fresenius Kabi is a global healthcare company that specializes in lifesaving medicines and technologies for infusion, transfusion and clinical nutrition. The company's products and services are used for the therapy and care of critically and chronically ill patients.

Its product portfolio comprises a range of highly complex biopharmaceuticals, clinical nutrition, medical technologies, and I.V. generic drugs. Within biopharmaceuticals, Fresenius Kabi offers, among others, biosimilar drugs with a focus on autoimmune diseases and oncology. The company's clinical nutrition offering includes a wide selection of enteral and parenteral nutrition products. In the segment of medical technologies, its offering includes vital disposables, infusions pumps, apheresis machines, cell therapy devices, and more.

With its corporate mission of "caring for life", Fresenius Kabi puts essential medicines and technologies in the hands of people who help patients and finds the best answers to the challenges they face.

Following its "Vision 2026", the company is furthermore committed to increase efficiencies in the therapy and care of patients and improve access to high-quality healthcare around the globe.

Fresenius Kabi aspires to be leading globally in its product segments – all for the benefit of patients, its customers, and its stakeholders.

For more information, please visit [www.fresenius-kabi.com](https://www.fresenius-kabi.com).

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This release contains forward-looking statements that are subject to various risks and uncertainties. Future results could differ materially from those described in these forward-looking statements due to certain factors, e.g., changes in business, economic and competitive conditions, regulatory reforms, results of clinical trials, foreign exchange rate fluctuations, uncertainties in litigation or investigative proceedings, and the availability of financing.

Fresenius Kabi does not undertake any responsibility to update the forward-looking statements in this release.

Management Board: Michael Sen (Chairman), Marc Crouton, John Ducker, Andreas Duenkel, Dr. Christian Hauer, Dr. Michael Schönhofen

Chairman of the Supervisory Board: Sara Hennicken

Registered Office: Bad Homburg, Germany

Commercial Register: Amtsgericht Bad Homburg - HRB 11654