Press Release

Martin Kunze
Corporate Communications

Fresenius SE & Co. KGaA
Else-Kröner-Straße 1
61352 Bad Homburg
Germany
T +49 6172 608-2115
F +49 6172 608-2294
martin.kunze@fresenius.com
www.fresenius.com

March 30, 2022

Fresenius Kabi receives European Commission approval for its pegfilgrastim biosimilar Stimufend®

- Fresenius Kabi's first biosimilar to be used in oncology
- Fresenius Kabi's second approved biosimilar in Europe, expanding its autoimmune disease and oncology focused product portfolio
- Stimufend® offers an affordable, high quality treatment option in Europe for cancer patients receiving chemotherapy to decrease the incidence of infection as manifested by febrile neutropenia.

Fresenius Kabi, a global healthcare company that specializes in pharmaceuticals, medical technologies and nutrition products for critical and chronic conditions, announced today that the European Commission (EC) granted marketing authorization for Stimufend®, the company's pegfilgrastim biosimilar, for all approved indications of the reference medicine.

Dr. Michael Schönhofen, Fresenius Kabi's Chief Operating Officer and member of the Fresenius Kabi Management Board, said: "*With the approval of this new biosimilar product in Europe, we are leveraging our heritage in oncology and expanding our oncology portfolio to better support the treatment experience and clinical outcomes for patients with cancer. We are proud to be "caring for life" and to continue to deliver high-quality and affordable therapies for cancer and autoimmune diseases, while easing the burden on local healthcare systems.*"

Stimufend® is the company's first approved molecule in its oncology biosimilar portfolio and its second biosimilar approved in Europe, thereby expanding its portfolio with an affordable and accessible supportive care medicine for patients with non-myeloid cancer who are receiving myelosuppressive chemotherapy. Stimufend®, developed by Fresenius Kabi's Swiss-based Biosimilars team in conjunction with other partners, stimulates the growth of certain white blood cells, which are essential to prevent or fight infections, a common life-threatening risk in patients receiving myelosuppressive chemotherapy. The company intends to launch the biosimilar in a prefilled syringe in several European markets over the coming months. Fresenius Kabi has also filed its pegfilgrastim biosimilar candidate for regulatory approval with the U.S. Food and Drug Administration (FDA), and the application is currently under review.

The approval for Stimufend, Fresenius Kabi's pegfilgrastim biosimilar is based on analytical, pharmacokinetic, pharmacodynamic, safety and immunogenicity data. It included the results of two pivotal clinical trials that showed an equivalent pharmacokinetic, pharmacodynamic and immunogenicity profile to the reference product in healthy volunteers. The safety profile of Stimufend® was also comparable to the reference product.

About Stimufend, a pegfilgrastim biosimilar

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). The reference product Neulasta®** is indicated in Europe to reduce the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes).

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

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

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

# # #

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 to help care for critically and chronically ill patients. Fresenius Kabi's product portfolio comprises a comprehensive range of I.V. generic drugs, infusion therapies and clinical nutrition products as well as the devices for administering these products. In the field of biosimilars, Fresenius Kabi focuses on autoimmune diseases and oncology. In 2019, the first biosimilar product by Fresenius Kabi was launched. Within transfusion medicine and cell therapies, Fresenius Kabi offers products for collection of blood components and extracorporeal therapies.

With its corporate philosophy of "caring for life", the company is committed to putting essential medicines and technologies in the hands of people who help patients and finding the best answers to the challenges they face.

Fresenius Kabi employs more than 41,000 people worldwide. In 2021, the company reported sales of more than €7.1 billion. Fresenius Kabi AG is a wholly owned subsidiary of the Fresenius SE & Co. KGaA healthcare group.

For more information visit the company's website at www.fresenius-kabi.com.

Management Board: Michael Sen (Chairman), Marc Crouton, John Ducker, Dr. Christian Hauer, Dr. Michael Schönhofen, Gerrit Steen
Chairman of the Supervisory Board: Stephan Sturm
Registered Office: Bad Homburg, Germany
Commercial Register: Amtsgericht Bad Homburg - HRB 11654