Press Release

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Fresenius Kabi's pegfilgrastim biosimilar candidate MSB11455 met its primary endpoints in the two pivotal clinical studies

Fresenius Kabi announced today that MSB11455, a biosimilar candidate of Neulasta®* (pegfilgrastim), met its primary endpoints in the two pivotal clinical studies. Both studies are designed to enable the application for marketing authorization in the EU and US.

The first study titled: "A Randomized, Double-blind, Crossover Study to Compare the Pharmacokinetic and Pharmacodynamic Bioequivalence of a Single Injection of MSB11455 and Neulasta® in Healthy Adult Subjects" met all primary pharmacokinetic endpoints, C_{max} and area under the curve (AUC), as well as the primary pharmacodynamic endpoints of absolute neutrophil count (ANC). Similar adverse events were found in both treatment groups.

The second study titled: "A Randomized, Double-blind, Parallel Group, Controlled Study to Compare the Immunogenicity and Safety of MSB11455 and Neulasta® in Healthy Adult Subjects" met its primary endpoints for immunogenicity. Positive anti-drug antibodies status was balanced between both treatment groups and no neutralizing antibodies were found. Similar adverse events were observed in both study arms.

Further details for both studies can be found on: https://clinicaltrials.gov

Dr. Michael Schönhofen, Member of the Fresenius Kabi Management Board and President of the Pharmaceuticals Division, said: “We have reached another important milestone in the development of our biosimilar pipeline. It is our belief that biosimilars will further strengthen the Fresenius Kabi commitment in caring for cancer patients.”

Dr. Michael Soldan, Head of the Business Unit Biosimilars, Pharmaceuticals Division, Fresenius Kabi said: “These results are encouraging and reinforce our commitment to develop high quality biosimilar solutions for patients in oncology and autoimmune diseases. It is one of the challenges of the healthcare systems worldwide to provide patients access to affordable, high-quality treatments for life-threatening diseases, and biosimilars will be an important part of the solution.“

About MSB11455, a biosimilar candidate of Neulasta® (pegfilgrastim)

MSB11455 is being developed as a biosimilar candidate of Neulasta® by Fresenius Kabi**. Neulasta® (pegfilgrastim) is a biologic therapy approved in the EU and US. In the US, 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. Neulasta® is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

* Neulasta® is a registered trademark of Amgen

** MSB11455 is not yet submitted to health authorities for approval.

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Fresenius Kabi is a global health care 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 medical devices for administering these products. Within transfusion technologies, Fresenius Kabi offers products for collection and processing of blood components and for therapeutic treatment of patient blood by apheresis systems. In the field of biosimilars, Fresenius Kabi develops products with a focus on oncology and autoimmune diseases. 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 over 36,000 people worldwide. In 2017 the company reported sales of more than €6 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

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.