

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

December 18, 2017

Fresenius Kabi Submits its First Biosimilar Marketing Authorization Application to European Medicines Agency for MSB11022, a biosimilar of adalimumab

Fresenius Kabi is publishing today that its first Marketing Authorization Application (MAA) has been submitted and been accepted for review by the European Medicines Agency (EMA) for MSB11022, a biosimilar candidate of Humira® (adalimumab). The application includes the results of the Phase III AURIEL-Psoriasis (PsO) study showing equivalent efficacy of MSB11022 to the originator Humira®.

This submission represents Fresenius Kabi's first biosimilar candidate submitted in the European Union. In 2017, Fresenius Kabi acquired the biosimilars business of Merck KGaA which comprises the entire development pipeline that has a focus on oncology and autoimmune diseases. Dr. Michael Schönhofen, Member of the Fresenius Kabi Management Board and President of the Pharmaceuticals Division, said: "With our future biosimilars products, we will help fill a vital need in health care. Patients, healthcare professionals and payers may benefit from access to a greater choice of state-of-the-art and affordable therapies."

"MSB11022 was developed as a therapeutic solution for patients with chronic inflammatory diseases and has the potential to play an impactful role in long-term disease management," said Michael Soldan, Head of the Business Unit Biosimilars, Pharmaceuticals Division, Fresenius Kabi. "This is an important step in the development of our entire biosimilar pipeline."

Fresenius Kabi's MAA submission includes analytical, pharmacokinetic, efficacy, safety and immunogenicity data. The Phase III study in moderate-to-severe plaque psoriasis met its primary endpoints showing clinical equivalence to adalimumab. Safety and immunogenicity of MSB11022 were also comparable to adalimumab in the clinical studies. Data to support the transition of adalimumab patients to MSB11022 are included in the MAA.

About MSB11022, a proposed biosimilar of Humira® (adalimumab)

MSB11022 is being developed as a biosimilar of adalimumab by Fresenius Kabi SwissBioSim using advanced analytical methods. Adalimumab is a biologic therapy approved in the EU for use in the treatment of several chronic conditions including plaque psoriasis, Crohn's disease, ulcerative colitis, juvenile idiopathic arthritis, psoriatic arthritis, rheumatoid arthritis, hidradenitis suppurativa and ankylosing spondylitis.

#

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 35,000 people worldwide. In 2016 the company reported sales of about €6 billion. Fresenius Kabi AG is a wholly owned subsidiary of the Fresenius SE & Co. KGaA health care 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 does not undertake any responsibility to update the forward-looking statements in this release.

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