

Press Release

Matthias Link
Corporate Communications

Fresenius SE & Co. KGaA
Else-Kröner-Straße 1
61352 Bad Homburg
Germany
T +49 6172 608-2872
F +49 6172 608-2294
matthias.link@fresenius.com
www.fresenius.com

February 1, 2019

Fresenius Kabi receives positive CHMP opinion for MSB11022, a biosimilar candidate of adalimumab

Fresenius Kabi announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion, recommending marketing authorization for MSB11022, a biosimilar candidate of Humira® (adalimumab)¹.

The positive CHMP opinion is based on a comprehensive data package submitted to the EMA in late 2017. The marketing authorization application included analytical characterization, and preclinical and clinical studies, assessing the similarity of MSB11022 to the originator molecule. Overall 237 healthy volunteers and 443 patients were randomized in the clinical development program.

“Obtaining this positive CHMP opinion is a significant achievement for Fresenius Kabi and reinforces our commitment to deliver our biosimilars portfolio to patients,” commented Dr. Michael Schönhofen, Member of the Fresenius Kabi Management Board and President of the Pharmaceuticals Division. “Further to the announced license agreement with AbbVie, if marketing authorization is granted by the European Commission, Fresenius Kabi will provide patients in the European

¹ Humira® is a registered trademark of AbbVie Biotechnology Ltd.

Union with an additional treatment option in all indications of the reference product (Humira®)“.

The European Commission (EC) will now decide on the approval of MSB11022 which is expected in the second quarter of 2019. If approved, the EC will grant a centralized marketing authorization, which will be valid in all member countries of the European Union (EU). Norway, Iceland and Liechtenstein are members of the European Economic Area. These countries will take corresponding decisions based on the EC's recommendation.

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

MSB11022 is being developed as a biosimilar of adalimumab by Fresenius Kabi SwissBioSim. Adalimumab is a biological 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 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.

Management Board: Mats Henriksson (Chairman), Marc Crouton, John Ducker, Chris Harrison, 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