Press Release

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Fresenius Kabi receives European Commission approval for adalimumab biosimilar IDACIO®

- IDACIO®* is Fresenius Kabi's first biosimilar approved by the European Commission in all indications of the reference product** in the areas of rheumatology, gastroenterology and dermatology
- IDACIO® has demonstrated equivalent pharmacokinetics, efficacy, safety and immunogenicity to the reference product in the clinical development program[1,2,3].
- IDACIO® will facilitate more patient access to effective treatment options in Europe***

Fresenius Kabi, a global healthcare company that specializes in lifesaving medicines and technologies, announced today that the European Commission (EC) granted marketing authorization for IDACIO®, an adalimumab biosimilar, for all indications of the reference medicine.

"Fresenius Kabi has a heritage of providing high-quality and affordable products to patients and the EC approval of IDACIO® is an exciting achievement for us, leading to our first entry into the European biosimilars market." said Dr. Michael Schönhofen, Member of the Fresenius Kabi Management Board and President of the Pharmaceuticals & Devices Division. "We are devoted to putting patients first, and we will focus our efforts to ensure patient access to IDACIO® within Europe."

The EC approval of IDACIO® was based on the totality-of-evidence detailed in the comprehensive data package submitted to the European Medicines Agency (EMA) including analytical, preclinical and clinical data in healthy volunteers and patients.

IDACIO® is the first approved molecule of the Fresenius Kabi biosimilars portfolio with a focus on autoimmune and oncology medicines. The EC approval of IDACIO® is an important milestone for Fresenius Kabi as a company, contributing to the advances in patient care, and for those who need alternative affordable treatment options.

About IDACIO®

IDACIO® was developed by Fresenius Kabi. The European Commission approved IDACIO® for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis including ankylosing spondylitis, psoriatic arthritis, adult and paediatric, plaque psoriasis, adult and adolescent hidradenitis suppurativa, adult and paediatric Crohn's disease, ulcerative colitis, adult and paediatric non-infectious uveitis[4].

1 Hyland E, et al. Comparison of the pharmacokinetcis, safety and immunogenicity of MSB11022, a biosimilars of adalimumab, with Humira® in healthy subjects. *Br J Clin Pharmacol*. 2016;82(4):983–932

2 Hercogova J et al. A randomized, double-blind trial comparing the efficacy, safety and immunogenicity of MSB11022, a proposed biosimilar of adalimumab, versus adalimumab originator in patients with moderate-to-severe plaque psoriasis. *Am Acad Dermatol*. 2018;79(3):AB21

3 Hercogova J et al. Safety, immunogenicity, and efficacy after a single switch from reference adalimumab to the proposed biosimilar MSB11022: Longterm results from a randomized, double-blind, 52-week, phase III study in moderate-to-severe plaque-type psoriasis patients *Am Acad Dermatol*. March 1-5, 2019 Washington DC: Poster 10554 (https://www.aad.org/eposters/)

4 SmPC data on file

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

** Humira®, a registered trademark of AbbVie Biotechnology Ltd.

*** The decision of the European Commission is valid in all the 28 member countries of the European Union plus in the European Economic Area (EEA) countries Norway, Iceland and Liechtenstein

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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.

Fresenius Kabi's biosimilar product development is focused 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 37,000 people worldwide. In 2018 the company reported sales of more than €6.5 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.