

Sandoz International
Industriestr. 25
83607 Holzkirchen, Germany
Tel: +49 8024 476 2596
Fax: +49 8024 476 2599
www.sandoz.com

Sandoz receives European Commission approval for Zessly[®] (infliximab) in gastroenterological, rheumatological and dermatological diseases

- *European Commission's (EC) approval based on comprehensive data package confirming that Zessly[®] matches safety, efficacy and quality of reference medicine*
- *Biosimilars such as Zessly enable earlier patient access to important medicines and positively impact healthcare systems*
- *Zessly is the third EC approval for a Sandoz biosimilar in 12 months*

Holzkirchen, Germany, May 24, 2018 – Sandoz, a Novartis division and the global leader in biosimilars, today announced that the European Commission (EC) has approved Zessly[®] (infliximab) for use in Europe.

Zessly is approved for use in all indications of the reference medicine^{†*} including rheumatoid arthritis, adult Crohn's disease, pediatric Crohn's disease, adult ulcerative colitis, pediatric ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis.

"The European Commission approval for Zessly is a key milestone in bringing this important medicine to appropriate patients," said Richard Francis, CEO, Sandoz. "Biosimilars, such as Zessly, help to address a significant unmet need for earlier patient access to biologic medicines and are at the heart of our Sandoz commitment to improving and extending lives."

The EC approval was based on review of a comprehensive development program, including analytical, preclinical and clinical data, which confirmed Zessly matched its reference medicine in terms of safety, efficacy and quality. The clinical Phase III confirmatory study in rheumatoid arthritis (REFLECTIONS B537-02) met its primary endpoint, demonstrating equivalent efficacy of Zessly to the reference medicine as measured by the American College of Rheumatology 20 (ACR20) response at Week 14.¹

As a Novartis division, Sandoz is well-positioned to lead the biosimilars industry based on its experience and capabilities in development, manufacturing and commercialization. Zessly is the sixth approved biosimilar medicine for Sandoz, with several more major oncology and immunology launches expected globally by 2020.

About Zessly[®] (infliximab)

Zessly blocks the action of tumor necrosis factor (TNF)-alpha in patients with certain autoimmune diseases in which excess TNF-alpha activity may be harmful or cause onset of disease. By blocking the action of TNF-alpha, infliximab inhibits an underlying cause of inflammation.

Disclaimer

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as "potential," "well-positioned," "can," "will," "expected," "commitment," "investigational," "portfolio," "launch," or similar terms, or by express or implied discussions regarding potential marketing approvals, launches, new indications or labeling for Zessly and the other investigational or approved biosimilar products described in this press release, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of

Sandoz International
Industriestr. 25
83607 Holzkirchen, Germany
Tel: +49 8024 476 2596
Fax: +49 8024 476 2599
www.sandoz.com

these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Neither can there be any guarantee that, if approved, such biosimilar products will be approved for all indications included in the reference product's label. Nor can there be any guarantee that Zessly will be successfully launched, or in any particular time frame. Neither can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; the particular prescribing preferences of physicians and patients; competition in general, including potential approval of additional biosimilar versions of such products; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures; litigation outcomes, including intellectual property disputes or other legal efforts to prevent or limit Sandoz from selling its products; general political and economic conditions; safety, quality or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Sandoz

Sandoz is a global leader in generic pharmaceuticals and biosimilars. As a division of the Novartis Group, our purpose is to discover new ways to improve and extend people's lives. We contribute to society's ability to support growing healthcare needs by pioneering novel approaches to help people around the world access high-quality medicine. Our portfolio of approximately 1000 molecules, covering all major therapeutic areas, accounted for 2017 sales of USD 10.1 billion. In 2017, our products reached well over 500 million patients. Sandoz is headquartered in Holzkirchen, in Germany's Greater Munich area.

Sandoz is on Twitter. Sign up to follow @Sandoz_global at http://twitter.com/Sandoz_Global.

Learn more about biosimilars: <https://www.sandoz.com/our-work/biopharmaceuticals>

Follow our blog at www.sandoz.com/makingaccesshappen.

References

1. Cohen, SB. A Randomized, Double-Blind Study Comparing PF-06438179/GP1111, a Potential Infliximab Biosimilar, and Infliximab, Both in Combination with MTX, As Treatment for Patients with Moderate to Severe Active RA Who Have Had an Inadequate Response to MTX Therapy. Available at: <http://acrabstracts.org/abstract/a-randomized-double-blind-study-comparing-pf-06438179gp1111-a-potential-infliximab-biosimilar-and-infliximab-both-in-combination-with-mtx-as-treatment-for-patients-with-moderate-to-severe-active/>. Accessed on 20 March 2018.

†*Remicade® is marketed by MSD in Europe and is a registered trademark of Janssen Biotech, Inc.

Sandoz acquired infliximab (PF-06438179) development, commercialization and manufacturing rights from Pfizer in February 2016 for the 28 European Union countries plus Norway, Iceland and Liechtenstein that form the European Economic Area (EEA). Under the terms of the divestment, Pfizer retains commercialization and manufacturing rights to infliximab (PF-06438179) in countries outside the EEA.

Sandoz International
Industriestr. 25
83607 Holzkirchen, Germany
Tel: +49 8024 476 2596
Fax: +49 8024 476 2599
www.sandoz.com

###

Novartis Media Relations

Central media line: +41 61 324 2200

E-mail: media.relations@novartis.com

Eric Althoff
Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Chris Lewis
Sandoz Global Communications
+49 8924 476 1906 (direct)
+49 174 244 9501 (mobile)
chris.lewis@sandoz.com

Michelle Bauman
Sandoz Global Communications
+1 973 714 8043 (mobile)
michelle.bauman@sandoz.com

Novartis Investor Relations

Central investor relations line: +41 61 324 7944

E-mail: investor.relations@novartis.com

Central
Samir Shah +41 61 324 7944
Pierre-Michel Bringer +41 61 324 1065
Thomas Hungerbuehler +41 61 324 8425
Isabella Zinck +41 61 324 7188

North America
Richard Pulik +1 212 830 2448
Cory Twining +1 212 830 2417