Sandoz receives positive CHMP opinion for proposed biosimilar infliximab

- Sandoz is seeking approval of biosimilar infliximab for use in all indications of its reference medicine across gastroenterology, rheumatology and dermatology
- Positive opinion is based on a comprehensive clinical and non-clinical data package that is expected to confirm that Sandoz biosimilar infliximab matches the reference medicine
- This recommendation marks the third CHMP positive opinion granted for a Sandoz biosimilar in 12 months, following Erelzi® and Rixathon®; Sandoz is on track to launch several biosimilars of major oncology and immunology biologics by 2020

Holzkirchen, Germany, March 23, 2018 – Sandoz, a Novartis division and the global leader in biosimilars, announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion for marketing authorization of infliximab, a proposed biosimilar to reference medicine infliximab† °.

The CHMP opinion recommends the proposed Sandoz biosimilar infliximab for the treatment of all indications of its reference medicine across gastroenterology, rheumatology and dermatology.

"Sandoz is proud to be at the forefront of diversifying the biologics treatment landscape by bringing biosimilar medicines to market for patients living with devastating autoimmune diseases," said Richard Francis, CEO, Sandoz. "Today’s positive CHMP opinion marks a strong step forward in our efforts to accelerate patient access to biologics, and specifically infliximab, through our leading portfolio."

The opinion is based on a comprehensive data package that is expected to confirm the biosimilarity of infliximab to the reference medicine with analytical, preclinical and clinical data matching across quality, efficacy and safety. The clinical Phase III confirmatory study in rheumatoid arthritis (REFLECTIONS B537-02) met its primary endpoint, demonstrating equivalent efficacy of proposed Sandoz biosimilar infliximab to the reference medicine as measured by the American College of Rheumatology 20 (ACR20) response at Week 14.¹

The European Commission (EC) will review the CHMP’s positive opinion. The EC has the authority to approve medicines for the European Union (EU). If approved, the EC will grant a centralized marketing authorization that will be valid in the 28 member countries of the EU. Norway, Iceland and Liechtenstein, as members of the European Economic Area (EEA), will take corresponding decisions based on the EC’s recommendation.

As the leader in biosimilars with five marketed products and several more major oncology and immunology launches expected globally by 2020, Sandoz acquired infliximab (PF-06438179) development, commercialization and manufacturing rights from Pfizer in February 2016 for the 28 EU countries plus Norway, Iceland and Liechtenstein that form the EEA. Under the terms of the divestment, Pfizer retains commercialization and manufacturing rights to infliximab (PF-06438179) in countries outside the EEA.

About Infliximab
Infliximab blocks the action of the protein tumor necrosis factor (TNF)-alpha in patients with certain autoimmune conditions in which excess TNF-alpha activity may be harmful or cause onset of disease.
By blocking the action of TNF-alpha, infliximab is believed to inhibit an underlying cause of inflammation.2

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 “positive opinion,” “recommendation,” “proposed,” “potential,” “step forward,” “can,” “will,” “plan,” “expected,” “anticipate,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “portfolio,” “launch,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the 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 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 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.
Follow our blog at www.sandoz.com/makingaccesshappen.
References


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

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

Tim Willeford
Sandoz Global Communications
+49 80 24 4760 (mobile)
tim.willeford@sandoz.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 Richard Pulik +1 212 830 2448
Pierre-Michel Bringer +41 61 324 1065 Cory Twining +1 212 830 2417
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