Sandoz receives positive CHMP opinion for proposed biosimilar adalimumab

- Sandoz is seeking approval of proposed biosimilar adalimumab for use in all reference medicine indications including those in rheumatology, gastroenterology and dermatology
- Positive CHMP opinion based on comprehensive analytical, preclinical and clinical data package that shows proposed biosimilar adalimumab matches reference medicine
- This recommendation marks the fourth positive CHMP opinion for a Sandoz biosimilar within 18 months

Holzkirchen, June 1, 2018 – Sandoz, a Novartis division and the global leader in biosimilars, today announced 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 a proposed biosimilar adalimumab.†

The CHMP opinion recommends the proposed Sandoz biosimilar adalimumab for treatment of all indications of its reference medicine† including rheumatoid arthritis, plaque psoriasis, Crohn's disease and ulcerative colitis.

"The positive CHMP opinion for our biosimilar adalimumab is an important milestone for the millions of patients looking to reclaim their health after an autoimmune disease diagnosis," said Richard Francis, CEO, Sandoz. "If approved by the European Commission, the introduction of our biosimilar adalimumab can help to expand access for those who need it most and give patients and doctors confidence in their chosen treatment option. Biosimilar adalimumab is backed by robust science, assured by manufacturing excellence and created with a deep understanding of customer needs."

The comprehensive data package comprises analytical, preclinical and clinical data, and demonstrates that proposed biosimilar adalimumab matches the reference biologic in terms of safety, efficacy and quality. A randomized, double-blind, three-arm parallel study was conducted to determine the pharmacokinetics, immunogenicity and safety of biosimilar adalimumab. The study met its primary objective in demonstrating PK bioequivalence. Additionally, clinical studies submitted for review include the Phase III confirmatory safety and efficacy study in patients with moderate to severe chronic plaque-type psoriasis (ADACCESS).†,1,2,3

The European Commission (EC) takes binding decisions on the authorization of medicines valid throughout the EU. It bases its decisions on scientific assessments by the CHMP, ensuring that medicines comply with high quality, safety and efficacy standards. If approved, the EC will grant a centralized marketing authorization that will be valid in the 28 countries that are members 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.

About adalimumab
In some cases of autoimmune disease, the immune system damages the body’s own tissues. Adalimumab can be a potentially appropriate treatment option for certain patients across a variety of indications. Overproduction of the protein tumor necrosis factor (TNF) happens as a result of inflammatory and immunological conditions such as rheumatoid arthritis, plaque psoriasis, Crohn's disease and ulcerative colitis. It can cause inflammation and destruction of tissues in the joints, mucosa or skin. Adalimumab works by targeting and blocking the protein that contributes to disease symptoms.†
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,” “can,” “will,” “believe,” “committed,” “investigational,” “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 1,000 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


† *Humira®* is a registered trademark of AbbVie Biotechnology Ltd.

###

**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  
+49 174 244 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