Sandoz biosimilar etanercept recommended by FDA advisory committee for approval to treat multiple inflammatory diseases

- Committee votes unanimously in favor of the Sandoz proposed biosimilar etanercept for all approved indications of the reference product
- Committee’s recommendation based on totality of evidence from global development program showing biosimilar etanercept is highly similar to Enbrel®

Holzkirchen, 13 July, 2016. Sandoz, a Novartis division and leader in biosimilars, announced today that the US Food and Drug Administration (FDA) Arthritis Advisory Committee recommended approval of its proposed biosimilar etanercept. The committee voted unanimously (20-0), in support of biosimilar etanercept for all five indications of the reference product, including rheumatoid arthritis (RA), plaque psoriasis (PsO), psoriatic psoriasis (PsA), ankylosing spondylitis (AS) and polyarticular juvenile idiopathic arthritis (JIA).

“We are encouraged by today's favorable advisory committee recommendation for our proposed biosimilar etanercept,” said Mark McCamish, M.D., Ph.D., Head of Global Biopharmaceutical Development, Sandoz. “As a global market leader in biosimilars, we are pleased to move one step closer toward our goal of expanding patient access with our proposed biosimilar etanercept, and look forward to continuing to work with the FDA as they complete their review of our application.”

The recommendation was provided after the presentation of data from a global development program including analytical, pre-clinical and clinical studies of the Sandoz biosimilar etanercept, which demonstrated biosimilarity to the reference product. Clinical studies included four comparative pharmacokinetic (PK) studies in 216 healthy volunteers† and a confirmatory efficacy and safety similarity study in 531 patients with chronic plaque psoriasis.

The FDA frequently seeks the advice of its advisory committees as it reviews and decides whether to approve applications, although the agency does not always follow their recommendations.

In December 2015, the European Medicines Agency (EMA) accepted Sandoz Marketing Authorization Application (MAA) for its biosimilar to Amgen’s EU-licensed Enbrel®, which seeks approval for the same indications as the reference product.

Sandoz is committed to providing patient access to high-quality, life-enhancing biosimilars. It is the pioneer and global market leader and currently markets three biosimilars worldwide. Sandoz has a leading pipeline with several biosimilars in late stage development, including assets in immunology and oncology. As part of the Novartis Group, Sandoz is well-positioned to lead the biosimilars industry based on its experience and capabilities in development, manufacturing and commercialization.

About GP2015

GP2015, the Sandoz proposed biosimilar of Enbrel®, has been studied in a global development program, which included a comprehensive comparison of GP2015 and Enbrel® at the analytical, non-clinical, and clinical levels, including data from four pharmacokinetic (PK) studies (GP15-101, GP15-102, GP15-103 and GP15-104*) involving a total of 216 healthy volunteers, as well as data from a confirmatory efficacy and safety study of 531 patients with moderate-to-severe chronic plaque psoriasis (PsO) (GP15-302). The development program also included five non-clinical studies. The proposed indications for GP2015 are identical to the indications for Enbrel® in rheumatoid arthritis (RA), PsO, psoriatic psoriasis (PsA), ankylosing spondylitis (AS) and polyarticular juvenile idiopathic arthritis (JIA).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as "recommended," "proposed," "recommendation," "encouraged," "goal," "look forward to," "committed," "pipeline," "late stage development," "well-positioned," or similar terms, or by express or implied discussions regarding potential marketing approvals for biosimilar etanercept, or potential marketing approvals for other products in the Sandoz biosimilar pipeline, or regarding potential future revenues.
from biosimilar etanercept and other products in the Sandoz biosimilar portfolio. Such forward-looking statements reflect the current views of the Group regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results expressed or implied by such statements. There can be no guarantee that biosimilar etanercept will be approved for sale in any market where it has been submitted, or submitted for sale in any additional markets, or at any particular time. Neither can there be any guarantee that, if approved, biosimilar etanercept will be approved for all indications included in the reference product label. Nor can there be any guarantee that any other product in the Sandoz biosimilar pipeline will be submitted or approved for sale in any market, or at any particular time. Neither can there be any guarantee that biosimilar etanercept or any other product in the Sandoz biosimilar portfolio will be commercially successful in the future. In particular, management’s expectations regarding biosimilar etanercept and such other biosimilar portfolio products could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; competition in general; global trends toward health care cost containment, including government, industry and general public pricing pressures; unexpected litigation outcomes; unexpected safety, quality or manufacturing issues; general economic and industry conditions, 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 more than 1000 molecules, covering all major therapeutic areas, accounted for 2015 sales of USD 10.1 billion. In 2015, our products reached more than 500 million patients and we aspire to reach one billion. Sandoz is headquartered in Holzkirchen, in Germany’s Greater Munich area.

*Enbrel® is a registered trademark of Immunex Corporation.
†GP15-104, one of the four PK studies that intended to demonstrate bioequivalence between GP2015 and EU-licensed Enbrel, was submitted as an amendment to the initial Biologics License Agreement at the request of European authorities.

For further information:

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

Tara Lanigan
Sandoz Global Communications
+49 (0) 172 8295 276
tara.lanigan@sandoz.com

Elizabeth Renz
Sandoz US Communications
+1 609-627-8558
+1 856-625-3959
Elizabeth.renz@novartis.com

Duncan Cantor
Sandoz Global Communications
+49 (0) 170 650 6067
duncan.cantor@sandoz.com

Novartis Investor Relations

Central phone:
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
Sloan Pavsner +1 212 830 2417

e-mail: investor.relations@novartis.com