Innovative study with three treatment switches confirms Sandoz biosimilar etanercept has equivalent efficacy to originator

- No clinically meaningful differences between biosimilar etanercept and the originator product in safety and efficacy over 52 weeks
- Innovative study design demonstrates switching between biosimilar etanercept and the originator product has no impact on safety and efficacy
- Sandoz biosimilar etanercept was approved by the FDA in August 2016 and is currently under review by the EMA

Holzkirchen, November 18, 2016 – Sandoz, a Novartis division, and the pioneer and global leader in biosimilars, today announced the publication of the EGALITY study in the British Journal of Dermatology. The confirmatory clinical safety and efficacy study shows Sandoz biosimilar etanercept is equivalent to the originator product, Enbrel, in more than 500 adult patients over 52 weeks.

The innovative design of the EGALITY study includes switched and continuous treatment arms. Patients who switched treatments crossed over between biosimilar etanercept and the originator product three times with no clinically meaningful differences in safety and efficacy.

"Sandoz recognizes that clinicians need robust data on switching to confidently prescribe biosimilars. In EGALITY the same patients received treatment with biosimilar etanercept and the originator product in an alternating fashion and these three treatment switches had no impact on safety and efficacy," said Malte Peters M.D., Head Global Clinical Development, Biopharmaceuticals, Sandoz. “This innovative study demonstrates that Sandoz is at the frontier of building trust and confidence in biosimilars to increase access to biologics for patients worldwide.” Peters continued.

The 52-week EGALITY study was a randomized, double-blind trial which involved 531 adult patients with moderate to severe plaque psoriasis. The study was carried out over 12 months in 74 dermatology clinical sites across Europe and South Africa and consisted of three treatment periods. In the first 12-week period, patients received biosimilar etanercept or the originator product. In the second period, patients with at least 50% improvement of psoriasis symptoms were re-randomized into four groups; the first two groups continued with their original treatment and other two switched to the alternate treatment every six weeks until week 30. In the third period, the patients continued to receive their last treatment at week 30 up to week 52.

From baseline to week 52, the percentage change in Psoriasis Area and Severity Index (PASI) score was comparable between biosimilar etanercept and the originator product. EGALITY also confirms a comparable safety profile of the two medicines over 52 weeks, with similar incidence rates of treatment-emergent adverse events seen in all study arms. The primary endpoint of achieving equivalence in PASI 75 response rates were met at week 12. These data were presented at the congress of the Psoriasis International Network (PIN), 2016.
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The FDA approved Sandoz biosimilar etanercept in August 2016 for all indications included in the label of the originator product, which is used to treat various inflammatory conditions including rheumatoid arthritis, plaque psoriasis and psoriatic arthritis. It is currently under regulatory review by the EMA after the submission was accepted in the second half of 2015.

Sandoz is committed to increasing patient access to high-quality, life-enhancing biosimilars. It is the pioneer and global leader in biosimilars and currently markets three biosimilars. Sandoz has a leading biosimilar pipeline and plans to launch five biosimilars of major oncology and immunology biologics across key geographies by 2020. As a division 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 Sandoz biosimilar etanercept
The Sandoz proposed biosimilar to Enbrel®, has been studied in a global development program, which included a comprehensive comparison of the biosimilar and Enbrel® at the analytical, pre-clinical, and clinical levels, including data from four pharmacokinetic studies (GP15-101, GP15-102, GP15-103 and GP15-104) involving a total of 216 healthy volunteers, as well as data from the confirmatory clinical safety and efficacy study EGALITY (GP15-302). The development program also included five pre-clinical studies.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by words such as “under review,” “committed,” “pipeline,” “plans,” “launch,” “well positioned,” “proposed,” or similar terms, or by express or implied discussions regarding potential marketing approvals for biosimilar etanercept or any of the other products in the Sandoz biosimilar pipeline, or regarding potential future revenues from biosimilar etanercept and the other products in the Sandoz biosimilar pipeline. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management 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 biosimilar etanercept or any of the other products in the Sandoz biosimilar pipeline will be submitted or approved for sale in any market, or at any particular time. Nor can there be any guarantee that biosimilar etanercept or any of the other products in the Sandoz biosimilar pipeline will be commercially successful in the future. In particular, management’s expectations regarding biosimilar etanercept and such other Sandoz biosimilar pipeline 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, including potential approval of additional versions of biosimilar etanercept; global trends toward health care cost containment, including government, industry and general public pricing pressures; unexpected litigation outcomes, including intellectual property disputes or other legal efforts to prevent or limit Sandoz from selling biosimilar etanercept or its other biosimilar products; the particular prescribing preferences of physicians and patients; general economic and industry conditions; unexpected safety, quality or manufacturing issues, 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 worldwide 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 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.

SANDOZ A Novartis Division
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.

References
2. Griffiths EM et al. GP2015, a proposed etanercept biosimilar, has equivalent efficacy, safety and immunogenicity to etanercept originator product in patients with chronic plaque-type psoriasis: 12 week results from the phase 3 EGALITY study. Poster presented at the Psoriasis 2016, 5th Congress of the Psoriasis International Network (PIN), July 07, 2016 (e-poster P222)

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