New data demonstrates Sandoz’ etanercept and rituximab biosimilar candidates bioequivalent to originator products

- Sandoz’ biosimilar etanercept candidate shows pharmacokinetic (PK) bioequivalence with no clinically meaningful differences in safety, tolerability and immunogenicity to the originator.¹
- Sandoz’ biosimilar rituximab candidate shows PK bioequivalence and similar pharmacodynamics (PD), safety, efficacy and immunogenicity.²
- Biosimilar etanercept candidate is under regulatory review by EMA* and FDA** and biosimilar rituximab candidate is undergoing EMA review.

Basel, June 9, 2016 – Sandoz, a Novartis division, and the pioneer and global leader in biosimilars, today announced results from two key studies comparing its biosimilar etanercept and rituximab candidates with the originator products - Enbrel®*** and MabThera®**** respectively. In both studies, the primary endpoints of achieving PK bioequivalence were met. The studies were presented at the Annual European Congress of Rheumatology (EULAR 2016) in London.¹² Etanercept and rituximab are indicated to treat autoimmune diseases such as rheumatoid arthritis. Rituximab is also indicated to treat hematological cancers like follicular lymphoma.

“Findings from these studies, along with additional data in our development programs, demonstrate that our biosimilar etanercept and rituximab candidates are highly similar to their originators,” said Malte Peters, Head Global Clinical Development, Biopharmaceuticals, Sandoz. “Access to biological therapies remains a challenge for many patients with immunological disorders such as rheumatoid arthritis and blood cancers like follicular lymphoma. If approved, our biosimilars could help broaden access to these vital therapies.”

The Phase I etanercept trial demonstrated PK bioequivalence and no clinically meaningful differences in safety, tolerability and immunogenicity between the biosimilar candidate and the etanercept originator product (Enbrel®).¹ No major safety signals were observed during the study.¹

The Phase II rituximab trial demonstrated PK bioequivalence and similar PD, safety, efficacy and immunogenicity between the biosimilar candidate and the rituximab originator product (MabThera®).² Adverse events related to both products were similar for both medicines.²

Sandoz’ biosimilar etanercept was accepted by the FDA and EMA for regulatory review in the last quarter of 2015. Sandoz is seeking approval for all indications included in the label of the originator product, which is used to treat a range of autoimmune diseases including rheumatoid arthritis and psoriasis.

Its biosimilar rituximab candidate was accepted by the EMA for regulatory review in May 2016. Sandoz is seeking approval for the same indications as the reference product with
the same presentations which is used to treat autoimmune diseases such as rheumatoid arthritis as well as a number of hematological cancers.

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 make 10 regulatory filings over a three-year period (2015-2017), having already submitted six and had one approved. 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 the Phase I etanercept study
(Annual European Congress of Rheumatology (EULAR 2016) ref: THU0145)
This study was a randomized, two-way crossover trial comparing the PK and safety of Sandoz' biosimilar etanercept candidate with originator etanercept (Enbrel®) in 54 healthy subjects, with a washout period of at least 35 days between administration of the two study drugs. Follow-up was undertaken for four weeks after the final study drug administration.

About the Phase II rituximab study
(Annual European Congress of Rheumatology (EULAR 2016) ref: FRI0222)
This was a prospective, randomized, double blind study in 173 patients with active rheumatoid arthritis not responsive to conventional therapies (disease-modifying antirheumatic drugs or TNF inhibitors). Primary analysis was performed at week 24 with efficacy and PD data collected to week 52, with safety follow-up ending 24 weeks after the last administration of study medication.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by words such as “under regulatory review,” “undergoing EMA review,” “could,” “seeking,” “committed,” “pipeline,” “plans,” “well-positioned,” or similar terms, or by express or implied discussions regarding potential marketing approvals for biosimilar etanercept or biosimilar rituximab, or potential marketing approvals for other products in the Sandoz biosimilar pipeline, or regarding potential future revenues from biosimilar etanercept, biosimilar rituximab 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 either or both of biosimilar etanercept and biosimilar rituximab will be approved for sale in any market, or submitted for sale in any additional markets, or at any particular time. Neither can there be any guarantee that, if approved, either or both of biosimilar etanercept and biosimilar rituximab will be approved for all indications included in their respective reference product labels. 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, biosimilar rituximab, or any other product in the Sandoz biosimilar portfolio will be commercially successful in the future. In particular, management’s expectations regarding biosimilar etanercept, biosimilar rituximab 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 manufacturing, quality or safety 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, a Novartis division, is a global leader in generic pharmaceuticals and biosimilars, driving sustainable access to high-quality healthcare. Sandoz supplies a broad range of affordable, primarily off-patent products to patients and customers around the globe. The Sandoz portfolio comprises approximately 1,100 molecules, which accounted for 2015 sales of USD 9.2 billion. Sandoz is headquartered in Holzkirchen, in Germany’s Greater Munich area. The company holds leading global positions in biosimilars as well as in generic anti-infectives, ophthalmics and transplantation medicines.

About Novartis
Novartis provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care and cost-saving generic pharmaceuticals. Novartis is the only global company with leading positions in these areas. In 2015, the Group achieved net sales of USD 49.4 billion, while R&D throughout the Group amounted to approximately USD 8.9 billion (USD 8.7 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 118,000 full-time-equivalent associates. Novartis products are available in more than 180 countries around the world. For more information, please visit http://www.novartis.com.

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References
2. Smolen J, et al. Pharmacokinetics, pharmacodynamics, safety and efficacy of proposed rituximab biosimilar (GP2013) vs EU-approved rituximab (RTX) in patients with rheumatoid arthritis: results from a randomized controlled trial (GP13-201) over 52 weeks. Poster presented at the Annual European Congress of Rheumatology (EULAR 2016), London, UK, 10 June 2016 (poster FRI0222)

*European Medicines Agency (EMA)
**Food and Drug Administration (FDA)
*** Enbrel® is a registered trademark of Pfizer in Europe and Amgen in the US.
****MabThera® is a registered trademark of Roche in Europe. The treatment is marketed as Rituxan in the US by Genentech.

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