New data reinforces clinical basis for switching to Sandoz biosimilar medicines

- Sandoz strengthens position as global leader in biosimilars with new immunology data from four clinical studies for proposed biosimilars adalimumab and rituximab
- Efficacy and safety of biosimilar adalimumab and safety of biosimilar rituximab match reference medicines in multiple-switching and retreatment study respectively
- Sandoz biosimilar adalimumab is under EMA review, while EC-approved Sandoz biosimilar rituximab is under review by the FDA

Holzkirchen, November 14, 2017 – Sandoz, a Novartis division and the global leader in biosimilars, today announces data from four clinical studies comparing its proposed biosimilar adalimumab and biosimilar rituximab with their reference medicines, Humira®* and MabThera®/Rituxan®† respectively.1-4

Studies included two innovative trials involving switching and two pharmacokinetic (PK) and pharmacodynamic (PD) studies. The results were presented at the American College of Rheumatology (ACR) Annual Meeting in San Diego, US.

Innovative studies involving switching:

- A Phase III confirmatory efficacy and safety study met its primary endpoint in the proportion of patients who achieved a 75% improvement at Week 16, as measured by the Psoriasis Area and Severity Index (PASI)5. Further the impact of switching between Sandoz biosimilar adalimumab and its reference medicine in patients with moderate-to-severe chronic plaque psoriasis was assessed. This innovative study design included continuous and ‘switch’ treatment arms. The study confirmed no clinically meaningful differences in efficacy, safety and immunogenicity between patients who continuously received biosimilar adalimumab, those who continuously received the reference medicine and those who switched between biosimilar adalimumab and reference medicine on multiple occasions.1

- A Phase III study evaluated rituximab retreatment in patients with rheumatoid arthritis (RA), who already had received reference rituximab for treatment of RA in the past. The study demonstrated that Sandoz biosimilar rituximab and the reference medicines match in terms of safety and immunogenicity for patients who switched from the reference medicine to biosimilar rituximab and for those who continued treatment with the reference medicine.2

"Healthcare systems have a significant opportunity to deliver much-needed savings by switching to high-quality biosimilars," said Mark Levick, MD PhD, Global Head of Development, Biopharmaceuticals, Sandoz. "Not only does the data presented demonstrate that our biosimilar adalimumab and biosimilar rituximab are important biologic alternatives for patients, but that physicians can switch to our biosimilars with confidence."

PK and PD data demonstrating equivalence:

- The Phase I PK study met its primary endpoint as bioequivalence was demonstrated between the biosimilar adalimumab and the reference medicine. The study demonstrated that Sandoz biosimilar adalimumab matched the reference adalimumab in terms of safety, tolerability and immunogenicity.3
The confirmatory PK and PD study in patients with RA met its primary endpoint by demonstrating PK bioequivalence and PD equivalence of biosimilar rituximab and the reference medicine. Study results further demonstrated the medicines have matching efficacy, safety and immunogenicity profiles.

Sandoz is committed to increasing patient access to high-quality biosimilars. We are the global leader in biosimilars, with five biosimilars currently marketed in various countries, as well as a leading global pipeline. Sandoz biosimilar rituximab, marketed as Rixathon®, was approved by the European Commission (EC) in June 2017 and is currently under review by the US Food and Drug Administration (FDA). Sandoz biosimilar adalimumab is currently being reviewed by the European Medicines Agency (EMA).

Sandoz is well positioned to continue leading the biosimilars industry based on our experience and capabilities in development, manufacturing and commercialization. As a division of Novartis, the first global healthcare company to establish a leading position in both innovative and off-patent medicines, we benefit strongly from this unique blend of experience and expertise in many different market environments.

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 “potential,” “can,” “will,” “plan,” “expect,” “anticipate,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “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 economic and industry conditions, including the effects of the persistently weak economic and financial environment in many countries; 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 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 2016 sales of USD 10.1 billion. In 2016, our products reached well over 500 million patients, and we aspire...
to reach one billion. 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

*Humira® is a registered trademark of AbbVie Biotechnology Ltd.
MabThera® is a registered trademark of F. Hoffmann-La Roche AG / Rituxan® is a registered trademark of BIOGEN MA INC (marketed as MabThera® in the EU and Rituxan® in the US).
Sandoz biosimilar rituximab has also been approved in Europe (European Economic Area (EEA). The European Economic Area (EEA) provides for the free movement of persons, goods, services and capital within the internal market of the European Union (EU) between its 28 member states, as well as three of the four member states of the European Free Trade Association (EFTA): Iceland, Liechtenstein, and Norway) as Riximyo® under a duplicate marketing authorization.*

References

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