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Sandoz regulatory submission for proposed biosimilar adalimumab accepted by FDA

- *Adalimumab is an anti-TNF medicine used to treat a range of immunological diseases¹*
- *The comprehensive data package provided is expected to demonstrate that Sandoz proposed biosimilar adalimumab matches the reference biologic medicine in terms of safety, efficacy and quality²⁻⁴*

Holzkirchen, January 16, 2018 – Sandoz, a Novartis division and the global leader in biosimilar medicines, announced today that the US Food and Drug Administration (FDA) has accepted its Biologics License Application (BLA), submitted under the 351 (k) pathway, for proposed biosimilar adalimumab to the reference medicine, Humira^{®*}.

“When patients are dealing with a chronic disease, it is imperative they have access to important medication that will help best manage their health.” said Mark Levick, Global Head of Development, Biopharmaceuticals, Sandoz. “The FDA’s acceptance of the regulatory submission for our biosimilar adalimumab brings us one step closer to offering a portfolio of options to the millions of patients in the US who suffer from an inflammatory disease.”

Adalimumab is indicated for the treatment of a number of inflammatory diseases including rheumatoid arthritis, plaque psoriasis, Crohn’s disease and ulcerative colitis¹. Rheumatoid arthritis alone affects approximately 1.5 million Americans with 200,000 new cases diagnosed each year^{5,6}. Women are disproportionately (3:1) affected by the disease⁵.

The comprehensive data package submitted to the FDA, which comprises analytical, preclinical and clinical data, is expected to demonstrate that Sandoz proposed biosimilar adalimumab matches the reference biologic in terms of safety, efficacy and quality. Clinical studies submitted to the FDA include a pharmacokinetic study in healthy volunteers and a Phase III confirmatory safety and efficacy study in patients with moderate to severe chronic plaque-type psoriasis (ADACCESS)²⁻⁴.

Sandoz is committed to increasing patient access to high-quality biosimilars. As the global leader in biosimilars, Sandoz has five biosimilars marketed in various countries worldwide, as well as a leading global pipeline. 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.

For more information, please visit <http://www.sandoz.com>

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

References

1. Humira[®] Highlights of Prescribing Information, 2002. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/125057s232lbl.pdf . Last accessed December 2017.
2. Blauvelt A et al. A randomized, double-blind, multicenter study to compare the efficacy, safety, and immunogenicity of a proposed adalimumab biosimilar (GP2017) with originator adalimumab Poster #5224 presented at the 2017 American Academy of Dermatology (AAD) Annual Meeting, 3-7 March 2017.
3. Blauvelt A et al. Long-Term Efficacy, Safety and Immunogenicity Results from a Randomized, Double-Blind, Phase III Confirmatory Efficacy and Safety Study Comparing GP2017, a Proposed Biosimilar, with Reference Adalimumab [abstract]. Arthritis Rheumatol. 2017; 69 (suppl 10). American College of Rheumatology (ACR) Annual Meeting, US, 3-9 November 2017.
4. Jauch-Lembach J, et al. Randomized, Double-Blind, Single-Dose, Three-Arm Parallel Trial to Determine the Pharmacokinetics and Safety of GP2017, EU- and US-Adalimumab in Healthy Male Subjects [abstract]. Arthritis Rheumatol. 2017; 69 (suppl 10). American College of Rheumatology (ACR) Annual Meeting, US, 3-9 November 2017.
5. Sholtzhauer, T.L. (2014). Living with Rheumatoid Arthritis. Available at: <https://books.google.co.uk/books?id=ouURBAAQBAJ&lpg=PR17&dq=200%2C000%20people%20diagnosed%20rheumatoid%20arthritis&pg=PR3#v=onepage&q=200,000%20people%20diagnosed%20rheumatoid%20arthritis&f=false>. Last accessed December 2017.
6. Arthritis Foundation. What is Rheumatoid Arthritis? Available at: <http://www.arthritis.org/about-arthritis/types/rheumatoid-arthritis/what-is-rheumatoid-arthritis.php>. Last accessed December 2017

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