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## **Sandoz proposed biosimilar adalimumab matches reference biologic in terms of efficacy and safety in long-term study**

- *51-week clinical study confirms that Sandoz proposed biosimilar adalimumab matches reference medicine Humira®\* safety and efficacy profile<sup>1</sup>*
- *Sandoz proposed biosimilar adalimumab is currently under review by the European Medicines Agency for the treatment of several immunological diseases*
- *Sandoz expects that approval of biosimilar adalimumab would further improve access to treatment for people living with immunological diseases*

**Holzkirchen, September 14, 2017** – Sandoz, a Novartis division and the pioneer and global leader in biosimilars, today announces new data on its proposed biosimilar adalimumab.

Data from a long-term study of patients continuously treated with the proposed biosimilar or the reference medicine show that efficacy and safety profiles of the two medicines match throughout 51 weeks of treatment in patients with moderate-to-severe chronic plaque psoriasis<sup>1</sup>. Results were presented at the 26<sup>th</sup> Congress of the European Academy of Dermatology and Venereology (EADV) in Geneva, Switzerland.

"Patient access to often critical and expensive biologic medicines is one of the key challenges facing healthcare systems in developed economies today," said Mark Levick MD, PhD, Global Head of Development, Biopharmaceuticals, Sandoz.

He added: "Biosimilars are fundamentally changing the ability of healthcare systems to address this challenge. This clinical data supports the safety and efficacy of our proposed biosimilar adalimumab and offers a real alternative for patients living with immunological diseases."

Sandoz is committed to increasing patient access to high-quality biosimilars. We are the pioneer and global leader in biosimilars, with five biosimilars currently marketed worldwide, as well as a leading global pipeline. We plan to launch a total of five major oncology and immunology biosimilars between 2017 and 2020, including adalimumab, which is currently being reviewed by the European Medicines Agency.

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.

### **About the study**

ADACCESS (NCT02016105) is a Phase III confirmatory randomized, double-blind, controlled, 51-week study to compare efficacy and safety between Sandoz biosimilar adalimumab and the reference medicine. The study consists of three treatment periods. During the first 17-week treatment period, eligible patients with active, but clinically stable, moderate-to-severe chronic plaque psoriasis were randomized to receive either biosimilar adalimumab or its reference medicine. In the second period, patients were re-randomized into four groups; the first two groups continued with their originally

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assigned treatment and the other two switched to alternating treatment every six weeks until Week 35. In the third period, patients received their initially assigned treatment up to Week 51<sup>1</sup>.

The Phase III confirmatory study demonstrates that Sandoz biosimilar adalimumab matches the reference medicine in terms of efficacy and safety up to Week 51. Psoriasis Area and Severity Index 75 (PASI 75) response rates for patients who received biosimilar adalimumab continuously throughout the study were 75.2% at Week 17 and 84.5% at Week 51, compared with 67.8% at Week 17 and 79.6% at Week 51 for patients who received continuous treatment with the reference medicine<sup>1</sup>. PASI 75 response represents an improvement of at least 75% in the severity of a patient's psoriasis. Investigator's Global Assessment (IGA) response rates were also similar between the two groups in the study throughout the 51 weeks. There were no clinically relevant differences in adverse events between the two treatment groups, and the immunogenicity profiles were similar<sup>1</sup>.

#### **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

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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.

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

### References

1. Blauvelt A et al. A phase III confirmatory study comparing GP2017 with reference adalimumab in patients with moderate-to-severe chronic plaque psoriasis: 51 week results from the ADACCESS study. Poster #P0405 presented at the 26<sup>th</sup> Congress of the European Academy of Dermatology and Venereology (EADV), 13–17 September 2017.

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