New data demonstrate Sandoz proposed biosimilar adalimumab has equivalent efficacy to reference medicine

- Sandoz proposed biosimilar adalimumab (GP2017) shown to have equivalent efficacy and a similar safety profile as reference medicine, Humira®
- Comprehensive development program show potential of GP2017 to treat inflammatory diseases, such as rheumatoid arthritis, inflammatory bowel disease and plaque psoriasis
- Study reinforces strength of Sandoz pipeline and its key role in the broader Novartis immunology portfolio

Holzkirchen, 6 March 2017 – Sandoz, a Novartis division, and the pioneer and global leader in biosimilars, today presented data for its proposed biosimilar adalimumab (GP2017). The Phase 3 confirmatory efficacy, safety and immunogenicity study met its primary endpoint demonstrating GP2017 has equivalent efficacy to the reference medicine, Humira®. Results were presented at the American Academy of Dermatology (AAD) in Orlando, Florida.

The primary endpoint of the study was the proportion of patients who achieved a 75% improvement at Week 16, as measured by the Psoriasis Area and Severity Index (PASI). Data from the study confirmed equivalent efficacy by demonstrating PASI 75 response rates of 67% for proposed biosimilar adalimumab and 65% for the reference medicine in patients with moderate to severe, chronic plaque psoriasis.

“Currently, it is estimated that as few as five percent of eligible psoriasis patients get the biologics they need” said Mark Levick, MD PhD, Global Head of Development, Biopharmaceuticals, Sandoz. “We are pleased the data reinforce the potential of our biosimilar adalimumab, if approved, to be another treatment option for moderate-to-severe chronic plaque psoriasis and other inflammatory diseases” Levick continued.

Results at week 17 demonstrated similar safety and immunogenicity between GP2017 and the reference medicine. Reported adverse events and the presence of anti-drug antibodies were similar across both treatment groups. Observed adverse events were in line with the reference medicine’s known safety profile.

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 worldwide. Sandoz has a leading biosimilar pipeline, with plans to file biosimilar adalimumab with the EMA and the FDA in 2017. Sandoz also 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 the study
The study (NCT02016105) is a Phase 3 randomized, double-blind, controlled, 51-week study to compare efficacy, safety and immunogenicity between GP2017 and Humira®. 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 GP2017 or Humira®. In the second period, patients were re-randomized into four groups; the first two groups continued with their originally assigned treatment and 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.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by words such as "proposed," "potential," "pipeline," "portfolio," "committed," "plans," "launch," "well-positioned," or similar terms, or by express or implied discussions regarding potential marketing approvals or labeling for biosimilar adalimumab or any of the other products in the Sandoz biosimilar pipeline, or regarding potential future revenues from biosimilar adalimumab 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 adalimumab 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. Neither can there be any guarantee that, if approved, biosimilar adalimumab will be approved for all indications included in the reference product's label. Nor can there be any guarantee that biosimilar adalimumab 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 adalimumab and such other Sandoz biosimilar pipeline products could be affected by, among other things, regulatory actions or delays or government regulation generally; the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; competition in general, including potential approval of additional versions of biosimilar adalimumab; global trends toward health care cost containment, including government, industry and general public pricing pressures; litigation outcomes, including intellectual property disputes or other legal efforts to prevent or limit Sandoz from selling biosimilar adalimumab or its other biosimilar products; the particular prescribing preferences of physicians and patients; general economic and industry conditions; 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.

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

References