New Sandoz biosimilar adalimumab data confirms switching from reference biologic has no impact on safety or efficacy

- Data show switching to Hyrimoz® (biosimilar adalimumab) from the reference medicine provides sustained efficacy with no new safety concerns in patients with moderate-to-severe rheumatoid arthritis

- ADMYRA data reinforces review summarizing 90+ publications, that switching from reference biologic to biosimilars does not impact safety, efficacy or immunogenicity

- Sandoz is the pioneer and a global leader in biosimilars with eight now approved – helping millions of patients worldwide access advanced biologic medicines

Holzkirchen, June 14 2019 – Sandoz, a Novartis division and a global leader in biosimilars, today announced data from the Phase III ADMYRA trial demonstrating that the efficacy and safety of biosimilar Hyrimoz® (adalimumab)* matches that of the reference medicine adalimumab** with no clinically meaningful differences in patients with moderate-to-severe rheumatoid arthritis (RA) with inadequate response to disease modifying antirheumatic drugs (DMARDs), including methotrexate (MTX). These data are being presented at the Annual European Congress of Rheumatology (EULAR) on 12-15 June in Madrid, Spain.

The 48-week study successfully met its primary and secondary endpoints showing sustained efficacy benefits in patients switched from reference adalimumab to Hyrimoz at Week 24. Treatment switch did not impact safety or immunogenicity as compared to the reference product alone. Similar efficacy was shown in patients treated with Hyrimoz or reference adalimumab as measured by Disease Activity Score-28 (DAS28) including high sensitivity C-reactive protein (CRP) and American College of Rheumatology response criteria (ACR20/50/70) at Week 12. Efficacy was maintained in switch patients at Week 48.

“Data from the ADMYRA trial reinforce our biosimilar adalimumab as an important biologic alternative for the millions of patients suffering from debilitating autoimmune diseases such as rheumatoid arthritis,” said Florian Bieber, Global Head of Development, Sandoz Biopharmaceuticals. “The data also adds to the strong body of evidence of 90+ publications demonstrating matching safety and efficacy when switching from a reference medicine to a biosimilar, giving healthcare providers additional confidence in prescribing biosimilars to their patients.”

More than 2.3 million people are diagnosed with RA in Europe and it is among the most common autoimmune disorders. The disease usually develops between the ages of 30 and 60 and affects the joints causing swelling, stiffness, pain and destruction.

“Rheumatoid arthritis is a systemic disease, which can progress beyond joints affecting lungs, heart and eyes,” said Prof. Dr. Hans-Peter Tony, Head Rheumatology and Immunology at
University Hospital Würzburg. “This data builds up on clinical evidence and will hopefully help conversations between physicians and patients to come to a more informed decision on switching to a biosimilar”, adds Dr. Marc Schmalzing, Deputy Head Rheumatology and Immunology at University Hospital Würzburg.

In 2018, Hyrimoz® was approved for use and launched in the EU and approved by the US Food and Drug Administration. Sandoz biosimilars are helping chronic-disease patients, particularly in immunology, oncology and endocrinology, access medicines sustainably and affordably worldwide. The division has a leading global portfolio with eight marketed biosimilars and a further 10-plus in development.

About ADMYRA
ADMYRA is a 48-week, double-blind, parallel-group, Phase III, multicenter study to evaluate efficacy and safety of Hyrimoz® in patients with moderate-to-severe RA with inadequate response to DMARDs, including MTX. ADMYRA enrolled 353 patients with ≥6 months’ diagnosis of moderate-to-severe RA, defined as DAS28-CRP score ≥3.2. Patients were treated with 40 mg/0.8 mL subcutaneous injections of Hyrimoz or reference adalimumab every other week from Day 1 to Week 22. From Week 24 all patients with at least a moderate DAS28-CRP response received Hyrimoz until the end of the trial. The primary endpoint was a change in DAS28-CRP from baseline at Week 12 in both reference and Hyrimoz treatment arms. The secondary endpoints were time-weighted average change from baseline in DAS28-CRP until Week 24, ACR20/50/70 response rates, EULAR responses, Boolean remission rates, quality of life scores, fatigue assessments, disease activity laboratory markers such as CRP and ESR as well as safety, local tolerability and immunogenicity (antidrug antibodies and neutralizing antibodies)1.

About Hyrimoz® (adalimumab)
Adalimumab, the active ingredient in Hyrimoz, is an inhibitor of tumor necrosis factor alpha (TNF-α)6, a protein that is overproduced in certain autoimmune conditions—including RA, plaque psoriasis, Crohn’s disease and ulcerative colitis—causing inflammation and tissue destruction in joints, mucosa or skin7. In some cases of autoimmune disease, the immune system damages the body’s own tissues. Hyrimoz targets and blocks the protein that contributes to disease symptoms5,6.

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 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. 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; global trends toward healthcare cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; our ability to obtain or maintain proprietary intellectual
property protection; the particular prescribing preferences of physicians and patients; general political and economic conditions; safety, quality or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, 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 and a pioneer in the emerging field of prescription digital therapeutics. Our purpose is to pioneer access to healthcare by developing and commercializing novel, affordable approaches that address unmet medical need. Our broad portfolio of high-quality medicines, covering all major therapeutic areas and increasingly focused on value-adding differentiated medicines, accounted for 2018 sales of USD 9.9 billion. Sandoz is headquartered in Holzkirchen, in Germany’s Greater Munich area.

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References


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** Humira® (adalimumab) is marketed by AbbVie Deutschland GmbH & Co. KG in Europe and Humira® is a registered trademark of AbbVie Biotechnology, Inc.