Sandoz receives US FDA approval for biosimilar Hyrimoz™ (adalimumab-adaz)

- **Biosimilar Hyrimoz™ (adalimumab-adaz) approved for all indications of reference medicine not protected by orphan exclusivity†**
- **Biosimilars are critical to sustaining US healthcare system, providing broader access to vital treatments for prevalent chronic conditions such as psoriasis and rheumatoid arthritis, which affect over eight million Americans combined**
- **Hyrimoz is third FDA-approved Sandoz biosimilar in US**

**Holzkirchen, Germany, October 31, 2018** — Sandoz, a Novartis division and the pioneer and global leader in biosimilars, today announced that the US Food and Drug Administration (FDA) approved its biosimilar, Hyrimoz™ (adalimumab-adaz). The FDA granted approval for the treatment of rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA) in patients four years of age and older, psoriatic arthritis (PsA), ankylosing spondylitis (AS), adult Crohn’s disease (CD), ulcerative colitis (UC) and plaque psoriasis (Ps).¹

“Biosimilars can help people suffering from chronic, debilitating conditions gain expanded access to important medicines that may change the outcome of their disease,” said Stefan Hendriks, Global Head of Biopharmaceuticals, Sandoz. “With the FDA approval of Hyrimoz, Sandoz is one step closer to offering US patients with autoimmune diseases the same critical access already available in Europe.”

The FDA approval of Hyrimoz was based on a comprehensive data package comprising analytical, preclinical and clinical research demonstrating that Hyrimoz matches the reference biologic in terms of safety, efficacy and quality. A randomized, double-blind, three-arm, parallel biosimilarity study confirmed the pharmacokinetics, immunogenicity and safety of Hyrimoz. The study met the primary endpoint, demonstrating bioequivalence for all primary pharmacokinetic parameters. A confirmatory efficacy and safety biosimilarity study (ADACCESS) demonstrated therapeutic equivalence in the sensitive indication of patients with moderate to severe chronic plaque-type psoriasis, with a similar safety and immunogenicity profile to the reference biologic.²,³,⁴

Rheumatoid arthritis is among the most common types of arthritis and affects approximately 1.3 million adults in the US.⁵ Psoriasis is the most prevalent autoimmune disease in the US, and according to recent studies, as many as 7.5 million Americans—approximately 2.2 percent of the population—have psoriasis.⁶

Sandoz is well-positioned to lead the biosimilars industry based on its experience and capabilities in development, manufacturing and commercialization. Hyrimoz is the company’s third approved biosimilar medicine in the US. Additional biosimilars for oncology and immunology indications are expected to launch globally across major regions by 2020.

**About Hyrimoz™ (adalimumab)**

Adalimumab, the active ingredient in Hyrimoz, is an inhibitor of tumor necrosis factor (TNF), a protein that is overproduced in certain autoimmune conditions—including rheumatoid arthritis, plaque psoriasis, Crohn’s disease and ulcerative colitis—causing inflammation and tissue destruction in joints, mucosa or skin. 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 symptoms.⁷
On October 11, 2018, Sandoz announced a global resolution of all intellectual property-related litigation with AbbVie concerning all indications of the proposed Sandoz biosimilar adalimumab for the reference medicine. The license enables patient access in the US to Hyrimoz (or Sandoz adalimumab or Sandoz biosimilar) as of September 30, 2023. As the pioneer and global leader in biosimilars, this settlement helps remove uncertainty regarding when our biosimilar will be available.

Hyrimoz is a trademark of Novartis AG.

Please see full Prescribing Information for Hyrimoz™ here.

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 “one step closer,” “well-positioned,” “expected,” “proposed,” “potential,” “can,” “will,” “investigational,” “portfolio,” “launch,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labelling for Hyrimoz and the other 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 Hyrimoz or the other investigational or approved biosimilar products described in this press release will be submitted or approved for sale or for any additional indications or labelling in any market, or at any particular time. Neither can there be any guarantee that, if approved, such other biosimilar products will be approved for all indications included in the reference product’s label. Nor can there be any guarantee that Hyrimoz or such other products will be commercially successful in the future. In particular, our expectations regarding Hyrimoz and such other 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 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 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 1,000 molecules, covering all major therapeutic areas, accounted for 2017 sales of USD 10.1 billion. In 2017, our products reached well over 500 million patients. 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.

References:

†Humira® is marketed by AbbVie in the US and is a registered trademark of AbbVie Biotechnology Ltd.

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