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MEDIA & INVESTOR RELEASE

Applications for proposed first-of-a-kind multiple sclerosis biosimilar natalizumab accepted by US FDA and EMA

- *Submission of proposed biosimilar supported by comprehensive package; aims to expand treatment access for people with multiple sclerosis in US and EU*
- *Multiple sclerosis (MS) is a chronic inflammatory and neurodegenerative disease that can drastically affect an individual's everyday life and requires life-long treatment*
- *Sandoz is committed to accelerating patient access to potentially life-changing, high-quality treatments, while generating savings for healthcare systems and patients*

Basel, July 25, 2022 – Sandoz, a global leader in generic and biosimilar medicines, announced today that the US Food and Drug Administration (FDA) has accepted its biologics license application (BLA) for a proposed first-of-a-kind biosimilar natalizumab, developed by Polpharma Biologics.

The application includes all indications covered by the reference medicine Tysabri® (natalizumab)* for relapsing forms of multiple sclerosis (MS) including clinically isolated syndrome (CIS), relapsing-remitting MS (RRMS), active secondary progressive disease in adults, and Crohn´s Disease.[1]

The European Medicines Agency (EMA) also accepted the marketing authorization application (MAA) for this proposed biosimilar natalizumab, as announced on July 15, covering treatment as a single disease-modifying therapy (DMT) in adults with highly active RRMS, the same indication as approved by the EMA for reference medicine Tysabri®*.[2]

The submitted biosimilar was developed to have the same intravenous (iv) dosage form, route of administration, dosing regimen and presentation as the reference medicine.

MS is a progressive chronic inflammatory and neurodegenerative disease of the central nervous system (brain and spinal cord) [3] that can drastically affect an individual's everyday life and requires life-long treatment. The disease has a wide range of symptoms, beginning with blurred vision, fatigue, weak limbs, unsteadiness and tingling sensations and leading to limited mobility and neurological decline.[4] Treatment cost and lack of access to effective treatment can create an additional burden for people with MS, their families and healthcare systems.[5]

"Thanks to advances in medicine over the last 20 years, we now have DMTs, which have become a cornerstone in the treatment of MS. However, access to affordable, high-quality treatment options is still a challenge," said Florian Bieber, Global Head of Biopharmaceuticals Development, Sandoz. "This is the first and only submission for a biosimilar natalizumab

medicine in both the US and Europe. If approved, this biosimilar has the potential to increase access while also delivering savings for healthcare systems."

The BLA and MAA include a comprehensive analytical, preclinical and clinical data package. The Phase I and Phase III Antelope studies in RRMS patients met their primary endpoints, showing that the biosimilar matches the reference medicine in terms of efficacy, safety and immunogenicity. Sandoz is committed to all aspects of the safe use of, and patient experience with, its proposed biosimilar natalizumab. This includes a JCV test and either a REMS (for the US) or RMP (for the EU) program, both of which will be subject to approval by the relevant health authority.

Sandoz entered into a global commercialization agreement for proposed biosimilar natalizumab with Polpharma Biologics in 2019. Under this agreement, Polpharma Biologics will maintain responsibility for development, manufacturing and supply. Through an exclusive global license, Sandoz has the rights to commercialize and distribute the product in all markets.

Sandoz is committed to helping millions of patients access biologic medicines sustainably in many different disease areas, including oncology and immunology. These submissions build on the already approved and well-established Sandoz global portfolio of eight marketed biosimilars and a further 15+ in various stages of development.

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," "may," "could," "would," "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. Neither can there be any guarantee that, if approved, such generic or 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 generic or biosimilar versions of such products; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; litigation outcomes, including intellectual property disputes or other legal efforts to prevent or limit Sandoz from selling its products; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; safety, quality, data integrity 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. Our purpose is to pioneer access for patients by developing and commercializing novel, affordable approaches that address unmet medical needs. Our ambition is to be the world's leading and most valued generics company. Our broad portfolio of high-quality medicines, covering all major therapeutic areas, accounted for 2021 sales of USD 9.6 billion.

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*Tysabri® is a registered trademark of Biogen MA, Inc.

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