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MEDIA & INVESTOR RELEASE

Sandoz receives European Commission approval for Tyruko® (natalizumab), first and only biosimilar for multiple sclerosis in Europe

- *Biosimilar Tyruko® approved for all indications of reference medicine, as first and only biosimilar* to treat *relapsing forms of multiple sclerosis (MS) in Europe*
- *Decision based on evidence from extensive analytical characterization demonstrating similarity of biosimilar with reference biologic, in addition to Phase I and confirmatory Phase III studies.*
- *Sandoz is committed to accelerate access to potentially life-changing treatments, while generating savings for healthcare systems and patients around the world*

Basel, September 26, 2023 — Sandoz, a global leader in generic and biosimilar medicines, today announced that the European Commission (EC) granted marketing authorization for the first and only biosimilar Tyruko® (natalizumab), developed by Polpharma Biologics.

The authorization covers treatment as a single disease-modifying therapy (DMT) in adults with highly active RRMS, the same indication as approved by the EC for the reference medicine Tysabri®* (natalizumab).[1]

Rebecca Guntern, President Europe, Sandoz, said: “Multiple sclerosis is a chronic condition with no cure at present and timely access to affordable, high-quality healthcare is therefore even more essential. Today’s approval brings us one step closer to reducing the burden of this disease for those living with multiple sclerosis in Europe by making the life-enhancing treatments they need more accessible.”

MS is a chronic inflammatory and neurodegenerative disease of the central nervous system that can drastically affect daily life.[2] Most people living with MS experience periods of new or worsening of existing symptoms known as relapses followed by periods of disease remission, when the symptoms improve partially or completely.[3] Early treatment with DMTs can change the course of a person’s MS and reduce future disability. However, access to DMTs is not universal; 72% of countries cite barriers to accessing DMTs and the cost of MS medicines is a barrier to access in many countries, according to the Atlas of MS Report.[4]

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

The comprehensive regulatory submission package included evidence derived from an extensive analytical and functional characterization, in addition to results from a Phase I PK/PD study and a confirmatory Phase III Antelope study in RRMS patients. Both studies met their primary endpoints, confirming that the biosimilar matches the reference biologic in terms of pharmacokinetics as well as efficacy, safety and immunogenicity. Tyruko® has the same strength/ dosage form, intravenous (IV) route of administration, dosing regimen and presentation as the reference medicine.

Sandoz is committed to helping millions of patients access critical and potentially life-changing biologic medicines sustainably and affordably across a range of areas including immunology, oncology, supportive care, and endocrinology. It has a leading global portfolio with eight marketed biosimilars and a further 25 assets in various stages of development. Since launching the first biosimilar in Europe in 2006, Sandoz has helped to create early and expanded patient access to life-altering medicines while increasing healthcare savings and creating competition that fuels further innovation.

About Tyruko® (natalizumab)
Tyruko® has been developed to match the reference medicine, an established, highly effective anti-α4 integrin monoclonal antibody used as disease modifying treatment in relapsing forms of multiple sclerosis (MS). Tyruko is indicated in the EU as a single disease-modifying therapy (DMT) in adults with highly active relapsing-remitting multiple sclerosis (RRMS).

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.

References
1. European Medicines Agency (EMA). Tysabri EPAR. Available from: https://www.ema.europa.eu/en/medicines/human/EPAR/Tysabri [Accessed August 2023]
2. MS International Federation. What is MS? October 2021. Available from: https://www.msif.org/about-ms/what-is-ms/ [Accessed August 2023]
3. Mayo Clinic. About Multiple Sclerosis. 2022. Available from: https://www.mayoclinic.org/diseases-conditions/multiple-sclerosis/symptoms-causes/syc-20350269. [Accessed August 2023]
4. MS International Federation. Atlas of MS 3rd edition: Clinical management of multiple sclerosis around the world. Available from: https://www.msif.org/wp-content/uploads/2021/05/Atlas-3rd-Edition-clinical-management-report-EN-5-5-21.pdf. [Accessed August 2023]

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

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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 covers all major therapeutic areas.

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