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MEDIA RELEASE

Sandoz launches first and only biosimilar for multiple sclerosis, Tyruko® (natalizumab), in Germany

- Tyruko® approved for all indications of reference medicine
- Tyruko® biosimilar to treat adults with highly active relapsing remitting multiple sclerosis (RRMS)
- Launch strengthens well-established Sandoz biosimilar portfolio in Europe

Basel, January 31, 2024 – Sandoz, the global leader in generic and biosimilar medicines, today announces the launch of Tyruko® (natalizumab) in Germany from February 1. Developed by Polpharma Biologics, Tyruko® is the first and only biosimilar to treat RRMS.

Tyruko® is indicated as a single disease-modifying therapy (DMT) in adults with highly active RRMS.[1] This is the same indication as approved by the European Commission for reference medicine Tysabri®*.[2]

"Early treatment with disease-modifying therapies can have a significant impact on people living with multiple sclerosis and their potential future disabilities. As the first and only biosimilar in this space, the availability of Tyruko® is a crucial milestone in improving access to effective and safe therapies for those in Europe that need them most."

Rebecca Guntern, President Europe, Sandoz

Access to novel high efficacy DMTs remains restricted with only roughly 20% of people living with MS in Europe able to make use of these innovative treatments. This number is significantly lower in Eastern European countries, roughly 3% to 4%.[3] This highlights that more must be done to ensure early and unrestricted access to these crucial medicines so that irreversible neurological damage and disease progression can be delayed.[3]

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Sandoz entered into a global commercialization agreement for biosimilar natalizumab with Polpharma Biologics in 2019. Under this agreement, Polpharma Biologics will maintain responsibility 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.

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, endocrinology and now also neurology. It has a leading global portfolio with nine marketed biosimilars and a further 24 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 improving healthcare through savings and creating competition that fuels further innovation.

About Tyruko® (natalizumab)

Tyruko® has been developed by Polpharma Biologics to match the reference medicine (Tysabri®*), an established, highly effective anti-α4 integrin monoclonal antibody. Tyruko® is indicated in the EU as a single DMT in adults with highly active RRMS.[1]

Disclaimer

This Media Release contains forward-looking statements, which offer no guarantee with regard to future performance. These statements are made on the basis of management's views and assumptions regarding future events and business performance at the time the statements are made. They are subject to risks and uncertainties including, but not confined to, future global economic conditions, exchange rates, legal provisions, market conditions, activities by competitors and other factors outside of the control of Sandoz. Should one or more of these risks or uncertainties materialize or should underlying assumptions prove incorrect, actual outcomes may vary materially from those forecasted or expected. Each forward-looking statement speaks only as of the date of the particular statement, and Sandoz undertakes no obligation to publicly update or revise any forward-looking statements, except as required by law.

References

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2. EMA. Tysabri® EPAR Product Information. Available from: https://www.ema.europa.eu/en/documents/product-information/tysabri-epar-product-information_en.pdf [Accessed October 2023]
3. Filippi, M et al. Early and unrestricted access to high-efficacy disease-modifying therapies: a consensus to optimize benefits for people living with multiple sclerosis, J Neurol. 2022; 269(3): 1670–1677. doi:10.1007/s00415-021-10836-8.

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

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About Sandoz

Sandoz (SIX: SDZ; OTCQX: SDZNY) is the global leader in generic and biosimilar medicines, with a growth strategy driven by its Purpose: pioneering access for patients. 22,000 people of more than 100 nationalities work together to bring Sandoz medicines to some 500 million patients worldwide, generating substantial global healthcare savings and an even larger total social impact. Its leading portfolio of more than 1500 products addresses diseases from the common cold to cancer. Headquartered in Basel, Switzerland, Sandoz traces its heritage back to the year 1886. Its history of breakthroughs includes Calcium Sandoz in 1929, the world's first oral penicillin in 1951, and the world's first biosimilar in 2006. In 2022, Sandoz achieved sales of USD 9.1 billion and core EBITDA of USD 1.9 billion.

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