Sandoz receives FDA approval for Tyruko® (natalizumab-sztn), first and only FDA-approved biosimilar for relapsing forms of multiple sclerosis

Aug 25, 2023

- *Biosimilar Tyruko®approved for all indications of reference medicine, with same dosing and administration schedule*
- *Sandoz continues to expand access to much-needed medications for patients in US, offering another treatment option to help control relapsing forms of multiple sclerosis*
- *US FDA approval based on robust Phase I and Phase III clinical studies; each met primary endpoints and showed Tyruko provides same risks and benefits in terms of efficacy, safety and immunogenicity as reference medicine*

Basel, August 25, 2023 – Sandoz, a global leader in generic and biosimilar medicines, today announced that the US Food and Drug Administration (FDA) has approved its biosimilar Tyruko® (natalizumab-sztn), developed by Polpharma Biologics. Tyruko is approved to treat all indications covered by the reference medicine and is the first and only FDA-approved biosimilar for relapsing forms of multiple sclerosis (MS).

Keren Haruvi, President North America, Sandoz Inc., said: “Of the nearly one million people in the US living with multiple sclerosis, hundreds of thousands experience disease relapse. Tyruko has the potential to extend the reach of natalizumab treatment for these patients, increase healthcare savings and fuel innovation through competition in the market.”

Tyruko is approved as a monotherapy to treat all indications covered by reference medicine Tysabri®* (natalizumab) for relapsing forms of MS, including clinically isolated syndrome (CIS), relapsing-remitting MS (RRMS) and active secondary progressive disease, as well as Crohn’s disease in adults.[1]

Bari Talente, the National MS Society’s Executive Vice President for Advocacy and Healthcare Access, said: “Access to affordable, high-quality healthcare is essential for people with multiple sclerosis to live their best lives. The approval of Tyruko, the first FDA-approved biosimilar disease-modifying treatment for people with relapsing forms of MS, is a milestone. Biosimilars are an important treatment option because they have no clinically meaningful differences from their reference medicines. Prescribing them can increase accessibility to affordable medications, improve adherence and help contain healthcare costs.”

The FDA granted approval based on a robust data package, including analytical, functional and clinical data. The approval is accompanied by labeling with safety warnings and a Risk Evaluation and Mitigation Strategy (REMS).

Tyruko has the same intravenous (IV) dosage form, route of administration, dosing regimen and presentation as the reference medicine. Sandoz is dedicated to all aspects of patient safety with Tyruko, which, upon launch, will be available through the Sandoz REMS program.

MS is a progressive chronic inflammatory and neurodegenerative disease of the central nervous system that can drastically affect daily life.[2] Most people with MS experience periods of new symptoms or relapses that improve partially or completely, followed by periods of disease remission.[3]

Sandoz entered into a global commercialization agreement for Tyruko with Polpharma Biologics in 2019. Under this agreement, Polpharma Biologics will maintain responsibility for development, manufacturing and supply of the active substance in Tyruko. Through an exclusive global license, Sandoz has the rights to commercialize and distribute it in all markets. Sandoz is committed to bringing this important medicine to US patients as soon as possible.

About Tyruko® (natalizumab-sztn)
Tyruko has been developed to be highly similar to the reference medicine, an established, highly effective anti-α4 integrin monoclonal antibody disease modifying treatment in relapsing forms of multiple sclerosis (MS). Tyruko is indicated in the US as a monotherapy for relapsing forms of MS, including clinically isolated syndrome (CIS), relapsing-remitting MS (RRMS) and active secondary progressive disease, as well as Crohn's disease in adults.[1] It is the first and only FDA-approved biosimilar for relapsing forms of MS.

INDICATIONS

Multiple Sclerosis (MS)
TYRUKO is indicated as monotherapy for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Natalizumab products increase the risk of progressive multifocal leukoencephalopathy (PML). Therefore, natalizumab is only available through dedicated Risk Evaluation and Mitigation Strategy (REMS) programs. When initiating and continuing treatment with TYRUKO, physicians should consider whether the expected benefit of TYRUKO is sufficient to offset this risk.

Crohn's Disease (CD)
TYRUKO is indicated for inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn's disease with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of TNF-α. TYRUKO should not be used in combination with immunosuppressants (e.g., 6-mercaptopurine, azathioprine, cyclosporine, or methotrexate) or inhibitors of TNF-α.

SELECT IMPORTANT SAFETY INFORMATION

WARNING: PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY
See full prescribing information for complete boxed warning.

- **Natalizumab products increase the risk of PML, an opportunistic viral infection of the brain that usually leads to death or severe disability.**
- **Risk factors for the development of PML include the presence of anti-JCV antibodies, duration of therapy, and prior use of immunosuppressants. These factors should be considered in the context of expected benefit when initiating and continuing treatment with TYRUKO.**
- **Monitor patients, and withhold TYRUKO immediately at the first sign or symptom suggestive of PML.**
- **Because of the risk of PML, TYRUKO is available only through a restricted distribution program called the TYRUKO REMS Program.**

CONTRAINDICATIONS: Patients who have or have had PML. Patients who have had a hypersensitivity reaction to natalizumab products.

WARNINGS AND PRECAUTIONS: *Herpes infections*: Life-threatening and fatal cases have occurred with herpes encephalitis and meningitis infections. Blindness has occurred in patients developing acute retinal necrosis. Discontinue TYRUKO if these infections occur and treat appropriately. *Hepatotoxicity*: Significant liver injury, including liver failure requiring transplant, has occurred. Discontinue TYRUKO in patients with evidence of liver injury. *Hypersensitivity reactions*: Serious hypersensitivity reactions (e.g., anaphylaxis) have occurred. Permanently discontinue TYRUKO if such a reaction occurs. *Immunosuppression/Infections*: Natalizumab products may increase the risk for certain infections. Monitor patients for development of infections due to increased risk with use of TYRUKO. *Thrombocytopenia*: Natalizumab products may cause thrombocytopenia. Monitor patients for bleeding abnormalities. Discontinue TYRUKO in patients with thrombocytopenia.

ADVERSE REACTIONS: The most common adverse reactions (incidence ≥10%) with natalizumab in the MS studies were headache, fatigue, arthralgia, urinary tract infection, lower respiratory tract infection, gastroenteritis, vaginitis, depression, pain in extremity, abdominal discomfort, diarrhea NOS, and rash. The most common adverse reactions (incidence ≥10%) in the CD studies were headache, fatigue, upper respiratory tract infections, and nausea.

USE IN SPECIFIC POPULATIONS: Pregnancy: Can cause fetal harm.

This is not the complete list of all the safety information for TYRUKO. Please click to see full Prescribing Information for TYRUKO.

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. Tyruko. Prescribing Information. Available at: **Prescribing Information**
2. MS International Federation. What is MS? October 2021. Accessed May 17, 2022. https://www.msif.org/about-ms/what-is-ms/
3. Mayo Clinic. About Multiple Sclerosis. 2022. Accessed July 7, 2023. Available from: https://www.mayoclinic.org/diseases-conditions/multiple-sclerosis/symptoms-causes/syc-20350269.

*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 vision is to be the world's leading and most valued generics company. Our broad portfolio of high-quality medicines covers major therapeutic areas.

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