First biosimilar approved to treat multiple sclerosis

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The U.S. Food and Drug Administration approved Tyruko (natalizumab-

sztn), the first biosimilar to Tysabri (natalizumab) injection, for the treatment of relapsing forms of multiple sclerosis, the agency announced Thursday.

Tyruko was approved to treat adults with clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. Like Tysabri, the biosimilar is also indicated for treating moderately to severely active Crohn disease in patients who do not respond to or tolerate conventional Crohn disease therapies or tumor necrosis factor-alpha inhibitors.

"Biosimilar medications offer additional effective treatment options that have the potential to increase access for people living with relapsing forms of multiple sclerosis," Paul R. Lee, M.D., Ph.D., of the FDA Center for Drug Evaluation and Research, said in an agency news release. "[This] approval could have a meaningful impact for patients managing their disease."

Approval of the biosimilar was based on data showing no clinically meaningful differences in safety and effectiveness between Tyruko and Tysabri. Prescribing information for both Tyruko and Tysabri includes a boxed warning of an increased risk for progressive multifocal leukoencephalopathy (PML). When prescribing these drugs, physicians should consider risk factors for PML development, including presence of anti-JCV antibodies, longer duration of therapy, and previous use of immunosuppressants, the FDA notes. Because of the risk for PML, Tyruko and Tysabri are available only through a restricted drug distribution program, which requires prescribers to be specially certified.

The prescribing information contains additional warnings of risks for herpes infections, thrombocytopenia, immunosuppression, serious hypersensitivity reactions, and hepatotoxicity. Side effects include headache and fatigue most commonly, in addition to arthralgia, urinary

tract infection, lower respiratory tract infection, gastroenteritis, vaginitis, depression, extremity pain, abdominal discomfort, diarrhea, and rash.

Approval of Tyruko was granted to Sandoz, Inc.

More information: More Information