Tyruko® (natalizumab-sztn) – New first-time biosimilar approval

- On August 24, 2023 the FDA announced the approval of Polypharma Biologics and Sandoz's Tyruko (natalizumab-sztn), biosimilar to Biogen's Tysabri® (natalizumab).
    - Tyruko is the first biosimilar approved for Tysabri.
- Tyruko and Tysabri share the following indications:
    - As monotherapy for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease, in adults
    - For inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn's disease (CD) with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of tumor necrosis factor-alpha (TNF-α).
- The approval of Tyruko is based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Tysabri.
- Tyruko has been approved as a biosimilar to Tysabri, *not as* an interchangeable product.
- Tyruko and Tysabri carry a boxed warning for progressive multifocal leukoencephalopathy (PML).
    - Because of the risk of PML, Tyruko and Tysabri are available only through a restricted distribution program under Risk Evaluation and Mitigation Strategy (REMS) called the Tyruko REMS Program and the TOUCH® Prescribing Program, respectively.
- Warnings and precautions for Tyruko include herpes infections, hepatotoxicity, hypersensitivity/antibody formation, immunosuppression/infections, laboratory test abnormalities, thrombocytopenia, and immunizations.
- The most common adverse reactions (≥ 10%) with Tyruko use in MS were headache, fatigue, arthralgia, urinary tract infection, lower respiratory tract infection, gastroenteritis, vaginitis, depression, pain in extremity, abdominal discomfort, diarrhea not otherwise specified, and rash.
- The most common adverse reactions (≥ 10%) with Tyruko use in CD were headache, upper respiratory tract infections, nausea, and fatigue.
- The recommended dosage of Tyruko for MS and CD is 300 mg intravenous infusion over one hour every four weeks.
    - When treating CD, Tyruko should not be used with concomitant immunosuppressants (eg, 6-mercaptopurine, azathioprine, cyclosporine, or methotrexate) or concomitant inhibitors of TNF-α. Aminosalicylates may be continued during treatment with Tyruko.

- If the patient with CD has not experienced therapeutic benefit by 12 weeks of induction therapy, Tyruko should be discontinued.

- Sandoz's launch plans for Tyruko are pending. Tyruko will be available as single-dose vials containing 300 mg/15 mL (20 mg/mL) solution.