Tascenso ODT® (fingolimod) – Expanded indication, new strength

- On December 9, 2022, the FDA approved Cycle Pharmaceuticals' Tascenso ODT (fingolimod), for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older.
    - Tascenso ODT was previously approved for this indication in pediatric patients 10 years of age and older and weighing less than or equal to 40 kg.
- In addition to the expanded indication in adults and pediatric patients 10 years of age and older and weighing more than 40 kg, the FDA approved a new 0.5 mg strength of Tascenso ODT.
    - Previously, Tascenso ODT 0.25 mg was the only approved strength.
- The efficacy of Tascenso ODT is based on the relative bioavailability of Tascenso ODT orally disintegrating tablets compared to fingolimod capsules (eg, Gilenya®) in healthy adults.
- In adults and pediatric patients 10 years of age and older weighing more than 40 kg, the recommended dosage of Tascenso ODT is 0.5 mg orally once-daily. In pediatric patients 10 years of age and older weighing less than or equal to 40 kg, the recommended dosage of Tascenso ODT is 0.25 mg orally once daily.
- Cycle Pharmaceuticals plans to launch both the 0.25 mg and 0.5 mg strengths of Tascenso ODT in the first quarter of 2023.