Tascenso ODT™ (fingolimod) – New formulation approval

- On December 23, 2021, the FDA approved Handa Neuroscience's Tascenso ODT (fingolimod) 0.25 mg orally disintegrating tablet, for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in pediatric patients 10 years of age and older and weighing less than or equal to 40 kg.

- Fingolimod is also available as a brand capsule (Gilenya®) carrying a similar indication to Tascenso ODT.

- The approval of Tascenso ODT is based on clinical studies conducted for Gilenya.

- Tascenso is contraindicated in patients who have:

    - In the last 6 months experienced myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization or Class III/IV heart failure
    - A history or presence of Mobitz Type II second-degree or third-degree atrioventricular block or sick sinus syndrome, unless patient has a functioning pacemaker
    - A baseline QTc interval ≥ 500 msec
    - Cardiac arrhythmias requiring anti-arrhythmic treatment with Class Ia or Class III anti-arrhythmic drugs
    - Had a hypersensitivity reaction to fingolimod or any of the excipients in Tascenso ODT. Observed reactions include rash, urticaria, and angioedema.
    - Concomitant use with other products containing fingolimod.

- Warnings and precautions for Tascenso ODT include bradyarrhythmia and atrioventricular blocks, infections, progressive multifocal leukoencephalopathy, macular edema, liver injury, posterior reversible encephalopathy syndrome, respiratory effects, fetal risk, severe increase in disability after stopping Tascenso ODT, tumefactive multiple sclerosis, increased blood pressure, malignancies, immune system effects following Tascenso ODT discontinuation, and hypersensitivity reactions.

- The recommended dosing for Tascenso ODT in pediatric patients 10 years of age and older weighing less than or equal to 40 kg, is 0.25 mg orally once daily.

    - Pediatric patients whose weight exceeds 40 kg after treatment initiation with Tascenso ODT should be switched to another fingolimod product approved for use in this weight group.

- Handa Neuroscience's launch plans for Tascenso ODT are pending. Tascenso ODT will be available as a 0.25 mg orally disintegrating tablet.