Gilenya® (fingolimod) – Expanded indication

- On May 12, 2018, Novartis announced the FDA approval of Gilenya (fingolimod), for the treatment of relapsing forms of multiple sclerosis (MS) in patients 10 years of age and older.
    - Previously, Gilenya was approved for the treatment of adult patients with relapsing forms of MS to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.
- MS is a chronic disorder of the central nervous system that disrupts the normal functioning of the brain, optic nerves and spinal cord through inflammation and tissue loss. While MS is mostly diagnosed in adults, children and adolescents with the chronic disease often experience more frequent relapses and brain lesions than adults with MS.
    - Two to five percent of people with MS have symptom onset before age 18 and estimates suggest that 8,000 to 10,000 children and adolescents in the U.S. have MS. In children, relapsing-remitting MS (RRMS) accounts for about 98% all cases.
    - In the U.S., MS affects around 400,000 people.
- The efficacy of Gilenya in pediatric patients 10 to less than 18 years of age with RRMS was studied in a double-blind study of 215 patients. Patients received Gilenya or Avonex® (interferon-beta-1a). The primary endpoint was the annualized relapse rate (ARR).
    - The ARR was significantly lower in patients treated with Gilenya (0.122) vs. patients who received Avonex (0.675) [relative reduction in ARR = 81.9%; $p < 0.001$].
- The recommended dosage of Gilenya in adults and pediatric patients 10 years of age and older weighing > 40 kg, is 0.5 mg orally once-daily.
- The recommended dosage of Gilenya in pediatric patients 10 years of age and older weighing ≤ 40 kg, is 0.25 mg orally once daily.