Gilenya® (fingolimod) – New Contraindication and Warnings

- On February 19, 2016, the FDA approved new updates to the Contraindications and Warnings and Precautions sections of the Gilenya (fingolimod) drug label, regarding hypersensitivity reactions and the risk of basal cell carcinoma (BCC).

- Hypersensitivity reactions, including rash, urticaria, and angioedema have been reported with Gilenya in the postmarketing setting. Thus, Gilenya is contraindicated in patients with history of hypersensitivity to fingolimod or any of its excipients. The Warnings and Precautions section has also been updated to reflect this new safety information.

- In addition, BCC is associated with use of Gilenya. In two-year placebo-controlled trials the incidence of BCC was 2% in patients on Gilenya 0.5 mg and 1% in patients on placebo.

- Healthcare providers and patients are advised to monitor for suspicious skin lesions. If a suspicious skin lesion is observed, it should be promptly evaluated.

- Other warnings and precautions of Gilenya include bradyarrhythmia and atrioventricular blocks, infections, progressive multifocal leukoencephalopathy, macular edema, posterior reversible encephalopathy syndrome, respiratory effects, liver injury, fetal risk, increased blood pressure, and immune system effects following Gilenya discontinuation.

- Gilenya is indicated for the treatment of patients with relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.