Bafiertam™ (monomethyl fumarate) – New drug approval

- On April 28, 2020, the FDA approved Banner Life Sciences' Bafiertam (monomethyl fumarate), 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.

- Bafiertam is bioequivalent to a prodrug of Tecfidera® (dimethyl fumarate), another drug used for relapsing forms of MS.

- The efficacy of Bafiertam is based upon bioavailability studies in healthy subjects comparing oral Tecfidera to Bafiertam.

- Bafiertam is contraindicated in patients with:

    — With known hypersensitivity to monomethyl fumarate, dimethyl fumarate, diroximel fumarate (Vumerity™), or to any of the excipients of Bafiertam. Reactions may include anaphylaxis or angioedema.
    — Taking dimethyl fumarate or diroximel fumarate.

- Warnings and precautions for Bafiertam include anaphylaxis and angioedema; progressive multifocal leukoencephalopathy; herpes zoster and other serious opportunistic infections; lymphopenia; liver Injury; and flushing.

- The most common adverse reactions (incidence for dimethyl fumarate [the prodrug of Bafiertam] ≥10% and ≥ 2% more than placebo) were flushing, abdominal pain, diarrhea, and nausea.

- The recommended starting dosage for Bafiertam is 95 mg twice a day orally for 7 days. After 7 days, the dosage should be increased to the maintenance dosage of 190 mg (administered as two 95 mg capsules) twice a day orally.

    — Blood tests are required prior to initiation of Bafiertam.
    — Administration of non-enteric coated aspirin (up to a dose of 325 mg) 30 minutes prior to Bafiertam dosing may reduce the incidence or severity of flushing.

- Banner Life Sciences' launch plans for Bafiertam are pending. Bafiertam will be available as a 95 mg delayed-release capsule.