Vumerity™ (diroximel fumarate) – New drug approval

- On October 30, 2019, Biogen and Alkermes announced the FDA approval of Vumerity (diroximel 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.

- Vumerity rapidly converts to monomethyl fumarate, the same active metabolite of Tecfidera® (dimethyl fumarate).

    — Vumerity and Tecfidera share the same indication.

- Vumerity was approved via the 505(b)(2) filing pathway. It included data from pharmacokinetic bridging studies comparing Vumerity and Tecfidera to establish bioequivalence, and relied, in part, on the FDA's findings of safety and efficacy for Tecfidera.

- Vumerity is contraindicated in patients with known hypersensitivity to diroximel fumarate, dimethyl fumarate, or to any of the excipients of Vumerity and in patients taking Tecfidera.

- Warnings and precautions for Vumerity include anaphylaxis and angioedema, progressive multifocal leukoencephalopathy, lymphopenia, liver injury, and flushing.

- The most common adverse reactions (≥ 10% and ≥ 2% more than placebo) with Vumerity use (using data from Tecfidera) are flushing, abdominal pain, diarrhea, and nausea.

- The starting dosage for Vumerity is 231 mg twice a day orally. After 7 days, the dosage should be increased to the maintenance dosage of 462 mg (administered as two 231 mg capsules) twice a day orally.

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

- Biogen's launch plans for Vumerity are pending. Vumerity will be available as a 231 mg delayed-release capsule.