Zeposia® (ozanimod) – New indication

- On May 27, 2021, Bristol Myers Squibb announced the FDA approval of Zeposia (ozanimod), for the treatment of moderately to severely active ulcerative colitis (UC) in adults.

- Zeposia is also approved 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.

- Zeposia is the first sphingosine 1-phosphate (S1P) receptor modulator approved for patients with UC. Other drugs in the class (eg, Gilenya® [fingolimod]) are only approved for MS.

- The approval of Zeposia for the new indication was based on two randomized, double-blind, placebo-controlled studies [UC Study 1 (induction) and UC Study 2 (maintenance) in adult patients with moderately to severely active UC. In UC Study 1, a total of 645 patients were randomized to either Zeposia or placebo for 10 weeks. The primary endpoint was clinical remission at week 10.

    — Clinical remission was achieved in 18% of patients receiving Zeposia vs. 6% of patients receiving placebo (treatment difference of 12, 95% CI: 8, 17; $p < 0.0001$).

- In UC Study 2, a total of 457 patients who received Zeposia in either UC Study 1 or in an open-label arm and achieved clinical response at week 10 were re-randomized and were treated with either Zeposia or placebo for 42 weeks, for a total of 52 weeks of treatment. The primary endpoint was the proportion of patients in clinical remission at week 52.

    — Clinical remission was achieved in 37% of patients receiving Zeposia vs. 19% of patients receiving placebo (treatment difference of 19, 95% CI: 11, 26; $p < 0.0001$).

- The most common adverse reactions (≥ 4%) with Zeposia use for UC were increased liver test, upper respiratory infection, and headache.

- The starting dosage for Zeposia for both of its indications is 0.23 mg once daily orally for days 1 to 4 and 0.46 mg once daily orally for days 5 to 7. After the initiation phase, the dosage should be increased to the maintenance dosage of 0.92 mg once daily orally.