FDA approves velsipity for moderate-to-severe ulcerative colitis in adults

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The U.S. Food and Drug Administration has approved Velsipity

(etrasimod) for adults with moderately to severely active ulcerative colitis (UC).

The approval was based on results from the ELEVATE UC phase 3 registrational program (ELEVATE UC 52 and ELEVATE UC 12) that included UC patients who had previously failed or were intolerant to at least one conventional, biologic, or Janus kinase inhibitor therapy.

In ELEVATE UC 52, 27.0% of patients receiving Velsipity achieved clinical remission versus 7.0% of patients receiving placebo at week 12, and at week 52, clinical remission was achieved by 32.0 and 7.0%, respectively.

In ELEVATE UC 12, 26.0% of patients receiving Velsipity achieved clinical remission versus 15.0% of patients receiving placebo. At week 12, all key secondary efficacy end points were met, including endoscopic improvement and mucosal healing.

The selective sphingosine-1-phosphate receptor modulator was approved at a 2mg recommended dose. The safety of Velsipity was consistent with previous studies, with the most common adverse reactions being headache, elevated liver tests, and dizziness (incidence ≥5%).

"Velsipity provides adults living with moderately-to-severely active UC the opportunity to achieve steroid-free remission with an oral, once-daily pill that has a favorable benefit-risk profile," Angela Hwang, Pfizer chief commercial officer and president of global biopharmaceuticals business, said in a statement.

Approval of Velsipity was granted to Pfizer.

More information: More Information