

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 $\geq 5\%$).

"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](#)

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