Disappointing Midway Trial Results for Emricasan as Treatment for NASH

At the 24-week mark of a 48-week trial, the treatment showed a trend toward a lack of efficacy.

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Halfway through a 48-week trial, Conatus Pharmaceuticals' emricasan showed a trend toward a lack of efficacy as treatment for non-alcoholic steatohepatitis (NASH), MedPage Today reports. While the trial must complete before a proper assessment of the drug's efficacy can be assessed, the 24-week results are not promising.

Presenting their findings at the 53rd International Liver Congress in Vienna, researchers conducted a multicenter randomized trial at 59 sites in the United States and the European Union. The study enrolled 263 people with NASH cirrhosis and an initial hepatic venous pressure gradient (HVPG) of at least 12 millimeters of mercury (mmHg).

Participants were 61 years old on average. Fifty-seven percent were women, and the majority were white. Eighty-five percent had type 2 diabetes. About 75 percent had compensated cirrhosis, the milder form of the severe liver disease.

The study randomized the participants into four even groups, which received either 5 milligrams, 25 mg or 50 mg of emricasan or a placebo.

After 24 weeks, there was no significant difference in the average HVPG between those who received any dose of emricasan compared with those who received the placebo. Nor was there any significant difference in average HVPG among those with cirrhosis. That said, among those with compensated cirrhosis who started the study with an HVPG of at least 16 mmHg, emricasan was associated with a significant reduction in that outcome.

Additionally, emricasan was associated with a significant reduction of various biomarkers of liver health, including cleaved cytokeratin-18, ALT and ASL liver enzymes and caspase 3/7.

Rates of treatment-related adverse health events were similar between those receiving emricasan and those receiving the placebo. A respective 17.9 percent and 11.9 percent of each group experienced serious treatment-related adverse events. Between 2 and 5 percent of each of the three emricasan groups experienced treatment-related adverse events and discontinued treatment, while none of those in the placebo group did so.

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