Seladelpar Shows Promise as Treatment for Primary Biliary Cholangitis

In a small ongoing study, the treatment showed an anti-cholestatic effect.

April 16, 2019 By Benjamin Ryan

Treatment with seladelpar showed an anti-cholestatic effect among those with primary biliary cholangitis (PBC) and compensated cirrhosis in an ongoing trial, MedPage Today reports.

Presenting their findings at the 53rd International Liver Congress in Vienna, researchers have been conducting a Phase II study of seladelpar. The current analysis concerns a subgroup of 25 people with Child-Pugh A cirrhosis (indicating a milder case of the severe liver disease).

The participants in this analysis were about 60 years old on average and had been diagnosed with PBC an average of 11 years prior. Most were women. All had had an inadequate response to or an intolerance for ursodiol as well as a total bilirubin of no more than 2 milligrams per deciliter.

After 52 weeks of treatment, the 14 participants who started treatment with 5 mg of seladelpar (and whose dose may have been increased up to 10 mg during the study, if warranted) experienced a 36 percent decline in their alkaline phosphatase production. The 11 people who started treatment at the 10 mg dose experienced a 43 percent reduction in their alkaline phosphatase production.

All those who started at 5 mg of seladelpar and 60 percent of those in the 10 mg group had an alkaline phosphatase level less than 1.67 times the upper limit of normal. (A test result higher than that threshold defined an inadequate response to ursodiol.) The average declines in ALT liver enzymes in these two groups was 31 percent and 50 percent, respectively. The median absolute changes in pruritus visual analogue scale were zero change and a decline of 25 in the two groups, respectively. Pruritus is the medical term for itching, a common symptom among those with PBC.

Three people experienced serious adverse events, all of which were deemed unrelated to seladelpar. The participants maintained stable total bilirubin, platelets, albumin and international normalize ratio. None of the participants experienced a progression of their cirrhosis to the decompensated stage, the more severe form of the condition.

To read the MedPage Today article, click here.
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