Elafibranor Shows Favorable Efficacy & Safety as PBC Treatment

Among those with primary biliary cholangitis, the investigational drug reduced alkaline phosphatase levels.

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Twelve weeks of the investigational drug elafibranor has shown promising results as a treatment for the autoimmune condition biliary cholangitis (PBC) in a mid-level trial.

Elafibranor is a peroxisome proliferator-activated receptor agonist. PBC involved inflammation and damage to the bile ducts that carry digestive fluid from the liver to the gallbladder.

Presenting their findings at the 53rd International Liver Congress in Vienna, researchers in the Phase II study enrolled 45 people with PBC who did not have cirrhosis and did not respond adequately to treatment with ursodeoxycholic acid (UDCA). This means they had an alkaline phosphatase (AP) level greater than 1.67 times the upper limit of normal (ULN).

The participants were randomized into three groups, which received 12 weeks of additional treatment with daily oral elafibranor at an 80 milligram dose, a 120 mg dose or a placebo.

At the end of the 12-week treatment period, those in the 80 mg of elafibranor group experienced a 48 percent decline in their average ALP, those in the 120 mg group experienced a 41 percent reduction and those in the placebo group experienced a 3 percent increase. A respective 67 percent, 79 percent and 6.7 percent of these three groups achieved a trio of positive outcomes: an ALP under 1.67 x ULN, a reduction in ALP of more than 15 percent and a total bilirubin within the normal limits.

The study also saw significant improvements in lipid and inflammatory markers as well as a trend toward less pruritis (itching) among those in the elafibranor groups.

The treatment was generally well tolerated and did not exacerbate or lead to pruritis (itching), a common symptom of PBC.

These findings, the investigators concluded, justify moving elafibranor into a Phase III trial including people with PBC who had an inadequate response to UDCA.

To learn more about primary biliary cholangitis, click here.

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