Intercept’s NASH Drug

A placebo-controlled study of obeticholic acid showed it improved liver fibrosis with no worsening of non-alcoholic steatohepatitis.

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A late-stage trial of Intercept Pharmaceuticals’ experimental non-alcoholic steatohepatitis (NASH) treatment found it was effective enough to warrant submission for Food and Drug Administration (FDA) approval.

The randomized, placebo-controlled trial is evaluating the safety and efficacy of Ocaliva (obeticholic acid) among 931 people with Stage F2 or F3 liver fibrosis (scarring) due to NASH, a condition in which fat buildup drives liver inflammation.

The participants were randomized into three even groups to receive a placebo, 10 milligrams of Ocaliva or 25 mg of the drug once daily. They received biopsies to determine their fibrosis severity at the study’s outset and after 18 months of treatment.

In the placebo, 10 mg and 25 mg groups, 12%, 18% and 23% of participants, respectively, experienced at least a one-stage improvement in fibrosis with no worsening of NASH. The difference in success rates between Ocaliva and the placebo was statistically significant, meaning it is unlikely to have occurred by chance. This improvement met a requirement the FDA established to consider the treatment successful.

Treatment was well tolerated, and any adverse health events experienced by the participants were generally mild to moderate.

The study’s lead author, Zobair M. Younossi, MD, PhD, a liver specialist at Inova Fairfax Medical Campus in Falls Church, Virginia, said these findings show that Ocaliva “also improves other important measures of liver health, including the key underlying drivers of NASH.”

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