Gilead’s Selonsertib Shows Promise as Treatment for NASH

The drug improved several measures of liver disease severity among those with non-alcoholic steatohepatitis in a clinical trial.

November 29, 2016

Gilead Sciences’ selonsertib (formerly GS-4997) improved various measures of liver disease severity among individuals with non-alcoholic steatohepatitis (NASH) and moderate to severe liver fibrosis in a recent midrange trial regardless of whether the drug was given with simtuzumab (SIM).

Researchers conducted a randomized, open-label Phase II trial of selonsertib alone or in combination with SIM among 72 people with NASH and fibrosis stages F2 (25 people) or F3 (47 people). Participants were randomized 2 to 2 to 1 to 1 to 1 to receive 24 weeks of 6 milligrams of the investigational apoptosis signal-regulating kinase 1 (ASK1) inhibitor selonsertib, 18 mg of selonsertib, 6 mg of selonsertib plus 125 mg of the monoclonal antibody SIM, 18 mg of selonsertib plus 125 mg of SIM or 125 mg of SIM. Selonsertib was given orally once a day, while SIM was given weekly through a subcutaneous injection (into the fat just below the skin).

Results were presented at the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in Boston.

Those who received selonsertib improved on several indicators of the severity of liver disease, including stage of fibrosis, progression to cirrhosis, liver stiffness and liver fat content. There were no differences in results based on whether participants received SIM.

Those whose fibrosis stage regressed showed reductions in their liver’s collagen content, the biochemistry of their liver (such as ALT liver enzymes) and a marker of apoptosis (a form of cell death) that indicated that selonsertib was working.

To read a press release about the study, click here.
