Gilead’s NASH Treatment Posts Disappointing Results

The placebo-controlled trial Phase III trial of selonsertib had sought to improve fibrosis while not worsening NASH.

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Gilead Sciences’ experimental non-alcoholic steatohepatitis (NASH) treatment selonsertib failed to reach its predefined one-year marker of success.

The Phase III STELLAR-4 study is a randomized, double-blind placebo-controlled trial evaluating the safety and efficacy of selonsertib in people with compensated cirrhosis (also known as severe, or F4, fibrosis) of the liver as a result of NASH. The study was open to participants between ages 18 and 70 years old.

Selonsertib is in a class of drugs known as inhibitors of apoptosis signal-regulating kinase 1 (ASK1).

A total of 354 people were randomized to receive 18 milligrams of selonsertib daily, while 351 received 6 mg of the drug and 172 received a placebo. The study was set to run for up to 240 weeks.

The study’s primary endpoint, which would determine whether the treatment was a success, was a decline of at least one stage in fibrosis—for example, from F4 to F3, or from cirrhosis to advanced fibrosis—without a worsening of NASH.

According to topline results Gilead has released, a total of 14.4 percent of those who took 18 mg of selonsertib and 12.5 percent of those who received 6 mg achieved the primary endpoint, proportions that were not statistically significantly different from the 12.8 percent of those in the placebo group who did so, meaning that any differences between the first two proportions and the latter proportion could have been driven by chance.

Selonsertib proved generally well tolerated. Its safety profile was similar to that seen in previous studies.

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