Following the encouraging interim results from a Phase II trial of sofosbuvir and ledipasvir, Gilead Sciences has announced plans for a Phase III trial of a fixed dose of the two drugs to treat people with hepatitis C virus (HCV), Reuters News reports. Called ION-3, the study will test a once-daily fixed-dose combination therapy of the two drugs both with and without ribavirin for eight weeks, as well as without ribavirin for 12 weeks. Six hundred non-cirrhotic, treatment-naive people with genotype 1 of the virus will participate in the trial.

“Based upon the encouraging data derived from LONESTAR, we are continuing to advance our research evaluating new drug combinations and shorter durations of all-oral therapy that have the potential to simplify treatment for those living with hepatitis C,” Norbert Bischofberger, PhD, executive vice president of research and development and the chief scientific officer at Gilead Sciences, said in release.

The Phase II study, called LONESTAR, gave the once-daily fixed-dose combination therapy both with and without ribavirin to 60 treatment-naive participants who did not have cirrhosis.

All 19 participants who underwent the therapy for 12 weeks—none of whom took ribavirin—experienced a sustained virologic response (SVR) four weeks after completing therapy; an SVR 12 weeks after therapy is considered a cure. Forty out of 41 of those in the eight week arms—21 took ribavirin, and 20 did not—experienced an SVR eight weeks after completing therapy. One relapse occurred in the arm in which participants did not take ribavirin.

There were another two arms of the LONESTAR study that included 40 participants who had previously failed a therapy, half of whom had compensated cirrhosis. All took the fixed-dose combination therapy for 12 weeks, and 21 of them took ribavirin as well. Twenty out of 21 of those who took ribavirin experienced an SVR four weeks after completing therapy, and 18 out of 19 of those who took only the fixed-dose combination therapy experienced an SVR four weeks after completing therapy.

To read a Gilead release, click here.
To read the Reuters story, click here.

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https://www.hepmag.com/article/sofosbuvir-PhaseIII-23926-2032275107