Experimental Hepatitis B Drug, JNJ-6369, Shows Promise in Early Trial

The drug has already advanced to a Phase IIa trial.

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An early ongoing study of an experimental treatment for hepatitis B virus (HBV), JNJ-6379, has highlighted the promise of the agent, MedPage Today reports. Researchers have already begun studying it in a more advanced trial.

Presenting their findings at the 52nd International Liver Congress in Paris, researchers conducted a Phase Ib study of the effects of JNJ-6379 on HBeAg-positive or HBeAG-negative people with chronic HBV who had a viral load greater than 2,000 and an ALT liver enzyme level no greater than 2.5 times that of their AST liver enzyme level.

The participants were randomized 3 to 1 to receive JNJ-6369 or a placebo for 28 days and followed for an additional eight weeks.

By the time of the liver conference presentation, the researchers had tested the drug in three groups of 12 people each, including those who had received: 25 milligrams of JNJ-6379 once daily (this group also initially received a 100 mg loading dose); 75 mg once daily; and 150 mg once daily. (The investigators are still evaluating a group that received 250 mg once daily.)

The median age of the 36 participants in the three groups was 42.5 years. Eighty-three percent were men. A quarter of them were HBeAg positive.

On day 29 of the study, all three groups saw a substantial drop in their hep B viral DNA and RNA. There were no significant changes in their HBsAg.

Grade 3 or greater adverse health events or abnormal lab test results occurred infrequently among the participants. Sixty-four percent of the study members experienced at least one adverse health event while on treatment, including a respective nine, six and eight of those who received 25 mg, 75 mg and 150 mg of JNJ-6379.

One person stopped treatment because of an ALT/AST liver enzyme flare (which did not occur along with a rise in bilirubin) that was likely related to JNJ-6379. No one experienced toxicities that suggested any of the dose levels used in the trial were too high.

During the eight-week posttreatment period of observation, the participants' HBV levels rebounded to nearly the levels seen when they started the trial.

Researchers have already begun a Phase IIa study of JNJ-6379 among individuals with hep B who have not been treated for the virus before as well as those with viral suppression thanks to treatment, including individuals who are HbsAg positive and HBsAg negative. This trial is testing JNJ-6379 either by itself or in combination with nucleoside analog medications.

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