Early Trial of Experimental Hepatitis B Agent Sets Stage for Cure Research

Researchers examined the effects of an agent known as RO7049389 among people with and without hepatitis B.

April 20, 2018 By Benjamin Ryan

An experimental hepatitis B virus (HBV) treatment, the core protein allosteric modulator RO7049389, showed robust activity against the virus and was safe and well tolerated, MedPage Today reports. These findings support further study of the agent as a possible component of a hep B cure regimen.

Presenting their findings at the 52nd International Liver Congress in Paris, researchers conducted a two-part study of RO7049389. The first part examined the safety, tolerability and pharmacokinetics (how the drug is metabolized) of the agent. The second part gave a variety of single doses of the drug, ranging from 150 to 2,000 milligrams, to five groups of people as well as multiple doses, ranging from 200 to 800 mg, to another five groups of people who did not have hep B. The second part of the study also gave twice daily doses of 200 mg of RO7049389 for 28 days to individuals with chronic hep B who had not been treated before.

Regardless of the dose, RO7049389 was rapidly absorbed and eliminated from the participants' plasma.

Fifty-five adverse health events were reported in 36 of the 75 participants in part one of the study. Part two saw 14 adverse health events in three of the seven participants who had chronic hep B. All adverse events were mild, and five of the events were considered related to RO7049389, including nausea, abdominal discomfort, rash and two cases of headache.

There were no serious adverse health events that prompted participants to stop taking the agent.

Six of the seven participants with HBV completed all 28 days of twice daily treatment. Among them, the median maximal decline in hep B viral load was 2.7 log10, or 99.8 percent. (A log10 is a power of 10, so a 1 log10 decline is 90 percent, a 2 log10 decline is 99 percent and so on.) Three of these individuals saw their viral load drop to an undetectable level. However, when they were taken off RO7049389, their viral loads rebounded nearly to the levels seen prior to treatment.

According to the researchers, these findings support further scientific inquiry into RO7049389 as a

potential component of a new hep B cure regimen.

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