Four in Five People With HIV and Hep C on Faldaprevir Achieve Early Treatment Success

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Interim results from a trial of the hepatitis C virus (HCV) protease inhibitor faldaprevir, given to people coinfected with hep C and HIV, have shown an 80 percent early success rate. However, there have also been three deaths, composing 1 percent of the study cohort. Boehringer Ingelheim announced these findings of its Phase III clinical trail at the 20th annual Conference on Retroviruses and Opportunistic Infections (CROI) in Atlanta. Called STARTVerso 4, this trial is an open-label, sponsor-blinded study to assess the efficacy and safety of faldaprevir in combination with pegylated interferon and ribavirin.

The study included 308 coinfected participants who, at the study outset, were either treatment-naive or had experienced a relapse following previous hep C therapy with pegylated interferon and ribavirin. Some of the study volunteers were taking antiretrovirals (ARVs) for HIV, while others were treatment-naive. Seventeen percent of the cohort had cirrhosis.

The cohort was divided into two groups: One received either 12 or 24 weeks of a 240 mg daily dose of faldaprevir; the second group received 24 weeks of a 120 mg daily dose of faldaprevir. Both groups also received either 24 or 48 weeks of pegylated interferon and ribavirin.

After 12 weeks of treatment, 84 percent of the participants across both groups had achieved an undetectable hep C viral load. The study investigators qualified 80 percent of the group as achieving early treatment success, a result that was consistent regardless of prior hep C treatment status or HIV therapy. Those who achieved early success were qualified for randomization into a shortened course of treatment, cutting its duration from 48 to 24 weeks.

Among the most frequent adverse events were nausea (37 percent), fatigue (33 percent), diarrhea (27 percent), headache (23 percent) and weakness (22 percent). Thirty-two participants (10 percent) experienced serious adverse events; three of the patients died during the study. Thus far, 18 patients have left the study because of adverse events.

All the patients maintained HIV viral suppression throughout the study.

In a separate presentation at CROI, Boehringer Ingelheim also presented results from three open-label Phase I studies of drug-drug interactions of faldaprevir with the HIV medications boosted Prezista (darunavir/ritonavir), Sustiva (efavirenz) and Viread (tenofovir). The studies found faldaprevir did not significantly affect the way the body processes those ARVs.

To read the Boehringer Ingelheim release, click here.

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