Faldaprevir Cures 80% of Hep C in First-time Treatment

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A Phase III trial of the protease inhibitor faldaprevir with pegylated interferon and ribavirin cured about 80 percent of treatment-naive people with genotype 1 of hepatitis C virus (HCV). Representatives from Boehringer Ingelheim Pharmaceuticals presented results from their STARTVerso 1 trial at the International Liver Congress, the 48th annual meeting of the European Association for the Study of the Liver (EASL) in Amsterdam.

The study was a double-blind, placebo-controlled trial involving 652 people with hepatitis C from Europe and Japan, including those with compensated cirrhosis. The participants were randomized to receive pegylated interferon and ribavirin in combination with a once-daily dose of either 120 milligrams of faldaprevir, 240 mg of the drug or a placebo. Those who had good early response to faldaprevir qualified to terminate the drug early.

In the first group, the 133 participants received 24 weeks of the placebo with interferon and ribavirin followed by 24 more weeks of just interferon and ribavirin.

In the second group, the 261 participants received 12 weeks of 120 mg of faldaprevir plus interferon and ribavirin. Those who had a good early response to therapy then took just interferon and ribavirin for an additional 12 weeks. Those who did not have good early response continued the original triple-drug regimen for an additional 12 weeks and then continued with just interferon and ribavirin for an additional 24 weeks, for 48 total weeks of treatment.

In the third group, the 262 participants received 12 weeks of 240 mg of faldaprevir with interferon and ribavirin followed by 12 weeks of just interferon and ribavirin. Those who had a good early response to therapy stopped treatment after 24 total weeks. Those who did not have a good early response received an additional 24 weeks of interferon and ribavirin, for 48 total weeks of treatment.

Those in the 120 mg and 240 mg faldaprevir treatment arms achieved respective sustained virologic response (SVR, considered a cure) rates of 79 and 80 percent 12 weeks after completing therapy. By comparison, just 52 percent of those participants receiving the placebo with interferon and ribavirin achieved a cure.

A respective 87 and 89 percent of those in the 120 mg and 240 mg arms had a good early

response to treatment and qualified for a shorter therapy duration. Among those who completed treatment early, a respective 86 and 89 percent were cured. Thus, nearly nine in 10 of those taking a faldaprevir-based regimen would qualify for only 24 weeks of treatment

To read the Boehringer Ingelheim release, click here.

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