Simeprevir Cures 80% of Hep C Participants in Phase III Studies

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The investigational NS3/4A protease inhibitor simeprevir cured four out of five people with genotype 1 of hepatitis C who also had compensated liver disease when the drug was taken with pegylated interferon and ribavirin, compared with a 50 percent cure rate for interferon and ribavirin alone. Janssen, which has jointly produced simeprevir with Medivir AB, announced findings from their QUEST-1 and QUEST-2 Phase III trials at the International Congress of the European Association for the Study of the Liver (EASL) in Amsterdam on April 24.

QUEST-1 and QUEST-2 included a respective 394 and 391 participants in 39 countries in the double-blind, placebo-controlled clinical trials. The participants were randomized to receive either simeprevir or a placebo for 12 weeks, plus pegylated interferon and ribavirin for 24 or 36 weeks. Eighty-five percent of QUEST-1 participants and 91percent of those from QUEST-2 who received simeprevir were able to take interferon and ribavirin for only 24 weeks as a result of good early response to therapy.

QUEST-1's average sustained virologic response (SVR, considered a cure) rate was 80 percent, and QUEST-2's was 81 percent.

The most common adverse events included fatigue, itch, headache, fever and flu-like illness. The rates of these side effects did not differ greatly between those taking simeprevir and those taking the placebo, suggesting that simeprevir does not add a significant side effect burden to that of interferon and ribavirin treatment alone.

On March 28, Janssen applied to the FDA for approval of simeprevir, based upon the results from these two studies as well as the PROMISE study, which gave the drug to participants who had relapsed after a previous interferon-based therapy.

To read the Janssen release, click here.