24 Weeks of Daclatasvir & Asunaprevir Cures 82-90% of 1b's

April 11, 2014

Bristol-Myers Squibb's daclatasvir and asunaprevir cured between 82 percent and 90 percent of people with genotype 1b of hepatitis C virus (HCV) after 24 weeks of treatment. Results from the Phase III global HALLMARK-Dual study of the NS5A inhibitor daclatasvir and the NS3 inhibitor asunaprevir were presented at the 49th annual meeting of the European Association for the Study of the Liver (EASL) in London.

A total of 205 treatment-naive study participants received 60 milligrams of daclatasvir once a day and 100 mg of asunaprevir twice a day for 12 weeks, while 102 participants received a placebo for that same time period. At the end of the 12 weeks, the treatment-naive group continued on the same regimen through to the 24-week mark while the placebo group entered another daclatasvir and asunaprevir study.

Another 235 participants fell into two categories: (1) those who were ineligible to take pegylated interferon and ribavirin or who were intolerant of the combination, or (2) those who had not responded to a previous attempt at hep C treatment. That overall group received the same daclatasvir and asunaprevir regimen for 24 weeks.

About 32 percent of everyone in the study had cirrhosis.

Ninety percent of the treatment-naive participants achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure). As for the previous non-responders and those ineligible to take pegylated interferon and ribavirin or who were intolerant of those drugs, 82 percent of both groups were cured.

"Not only was the daclatasvir and asunaprevir regimen highly effective among study participants, it was also very well tolerated, even among sicker patients with more advanced liver disease and higher unmet needs," said lead study investigator Michael P. Manns, MD, director of the department of gastroenterology, hepatology and endocrinology at Hannover Medical School in Hannover, Germany. "Despite a rapidly evolving HCV treatment paradigm, physicians and patients remain in need of new all-oral, interferon- and ribavirin-free regimens that have the potential to achieve virologic cure across a broad range of patients, including those with advanced liver disease and cirrhosis."

Indeed, cirrhosis did not appear to have an appreciable effect on treatment outcome: Eighty-four percent of the cirrhotic and 85 percent of the non-cirrhotic participants achieved an SVR12.

The regimen was generally well tolerated, with headache the most common side effect, experienced by a quarter of all participants.

To read the press release, click here.
