BMS Submits First Interferon-Free Hep C Treatment in Japan

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Bristol-Myers Squibb has submitted for approval in Japan the dual combination therapy of daclatasvir and asunaprevir as the world's first interferon- and ribavirin-free treatment for hepatitis C virus (HCV). The pharmaceutical company announced the submission, along with data from a Phase III study of those with genotype 1b of the virus on which the regulatory filing was based, at the 64th Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in Washington, DC.

"With our submission in Japan, we are pleased to be one step closer to bringing a potential new treatment option to the many people living with HCV in that country," Brian Daniels, MD, senior vice president of global development and medical affairs, research and development at BMS, said in a release. "The all-oral regimen of daclatasvir plus asunaprevir in this study represents the potential for a significant advance in the treatment of HCV infection in Japan."

The Phase III, open-label, parallel group study of Japanese people with genotype 1b of hep C included 135 participants who were interferon-ineligible or intolerant and 87 who were previous nonresponders to interferon-based treatment. They all took 60 milligrams of daclatasvir once a day and 100 mg of asunaprevir daily for 24 weeks.

At 24 weeks after completing treatment, 87.4 percent (118 out of 135 participants) of the interferon-ineligible or intolerant participants achieved a sustained virologic response rate (SVR, considered a cure), and 80.5 percent (70 out of 87) of the previous nonresponders achieved an SVR.

There were no deaths in the study, which had a discontinuation rate of 12.6 percent. A total of 5.9 percent experienced serious adverse side effects. The most common adverse side effects were nasal passage inflammation in 30.2 percent of participants, increased ALT liver enzymes (15.8 percent), increased AST enzymes (12.6 percent), headache (15.8 percent), diarrhea (9.9 percent) and fever (12.2 percent).

To read the BMS release, click here.

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