Janssen Submits Hep C Antiviral Simeprevir to FDA for Approval

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Janssen Research & Development LLC has submitted its investigational NS3/4A protease inhibitor simeprevir to the U.S. Food and Drug Administration for approval for treatment of genotype 1 of hepatitis C virus (HCV), to be taken with pegylated interferon and ribavirin.

The application is supported in part by data from three Phase III studies of simeprevir, including: QUEST-1; QUEST-2, which studied the drug in treatment-naive participants; and PROMISE, which gave the drug to people who had relapsed after a previous interferon-based hep C antiviral treatment. In all of these studies, participants took simeprevir for 12 weeks plus pegylated interferon and ribavirin for 24 or 48 weeks. Efficacy data from these studies will be released at the International Liver Congress of the European Association for the Study of the Liver (EASL) in Amsterdam this week.

“Hepatitis C is a complicated disease, and genotype 1 hepatitis C can be particularly difficult to cure. Given the complexity and diversity of the patient population, physicians need multiple options to provide their patients a chance at treatment success,” Wim Parys, global head of development, infectious diseases and vaccines at Janssen, said in a release. “The U.S. filing represents an important step forward in bringing simeprevir to market and in helping to battle this challenging disease.”

Janssen developed simeprevir in partnership with Medivir AB.

To read the Medivir release, click here.