FDA Gives Hep C Drug Simeprevir Priority Review

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The U.S. Food and Drug Administration (FDA) has given Janssen Research & Development priority review status for its investigational hepatitis C therapy simeprevir. Janssen submitted its New Drug Application (NDA) in the end of March for approval of the NS3/4A protease inhibitor for use with pegylated interferon and ribavirin among those with genotype 1 of hep C who have compensated liver disease.

The FDA grants priority review to drugs that may offer a major advance in treating a condition. Currently, there are two protease inhibitors approved to treat hep C, Incivek (telaprevir) and Victrelis (boceprevir). By law, the FDA review will begin about 60 days after the NDA with a goal of completing the process within six months. Thus, the review will start at the end of May and should be completed by the end of November.

Janssen submitted its NDA for simeprevir based in part upon results from three Phase III studies: QUEST-1 and QUEST-2, which studied the drug in treatment-naive people with hep C, and PROMISE, which gave simeprevir to those who had relapsed after a previous interferon-based treatment for the virus.

To read the Janssen release, click here.

To read the Fox Business story, click here.
