Simeprevir Closer to Approval After FDA Panel Recommendation

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Simeprevir, an investigational drug to treat hepatitis C virus (HCV), is now in the home stretch for a likely approval in late November following a unanimous recommendation from a U.S. Food and Drug Administration panel, Bloomberg.com reports. The FDA's Antiviral Drugs Advisory Committee voted 19 to 0 to recommend approval for Janssen Research & Development's simeprevir, to be given once a day in a 150 milligram capsule to treat genotype 1 of the virus. The drug received priority review status from the FDA in May.

"We are pleased with the positive recommendation from the advisory committee for simeprevir and appreciate the rigorous review of our data," Katia Boven, MD, medical department head of infectious diseases and vaccines at Janssen, said in a release. "It is our hope that the FDA will consider this recommendation and, upon completion of its review process, make simeprevir available to patients with genotype 1 chronic hepatitis C."

The panel based its recommendation upon findings from several Phase III studies: QUEST-1 and QUEST-2, in which about 80 percent of treatment-naive study participants achieved a sustained virologic response (SVR, considered a cure), and PROMISE, in those who had relapsed after a prior interferon-based treatment. The Phase IIb ASPIRE study of the drug in those who had previously not responded to treatment also played into the decision.

To read the Bloomberg story, click here.

To read a press release by Johnson & Johnson (Janssen is a pharmaceutical company of Johnson & Johnson), click here.

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