FDA Grants Priority Review to New Gilead Hep C Combo Tablet

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The U.S. Food and Drug Administration (FDA) has granted priority review status to Gilead Sciences' investigational pangenotypic hepatitis C virus (HCV) fixed-dose combination tablet, which includes Sovaldi (sofosbuvir) and velpatasvir. The designation secures a target decision date of June 28.

Gilead applied for approval of Sovaldi/velpatasvir on October 28 to treat those with genotypes 1 through 6 of hep C.

The FDA has already given the combination tablet a breakthrough therapy designation, which is given to investigational therapies that may offer major advances over existing treatments.

Sovaldi, which was approved in October 2013, is a nucleotide analog polymerase inhibitor. Velpatasvir is a pan-genotypic NS5A inhibitor.

To read the Wall Street Journal article, click here.

To read a Gilead press release on the designation, click here.
