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FDA approves Gilead's Harvoni for Hep C

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Singapore: Gilead Sciences has recieved US Food and Drug Administration (FDA) approval for Harvoni (ledipasvir 90 mg/sofosbuvir 400 mg), the first once-daily single tablet regimen for the treatment of chronic hepatitis C genotype 1 infection in adults.

Harvoni combines the NS5A inhibitor ledipasvir with the nucleotide analog polymerase inhibitor sofosbuvir, approved under the tradename Sovaldi in December 2013.

Harvoni's efficacy has been established in patients with chronic hepatitis C virus (HCV) genotype 1 infection, with a treatment duration of eight, 12 or 24 weeks depending on prior treatment history, cirrhosis status and baseline viral load.

The FDA had granted Harvoni a priority review and breakthrough therapy designation, which is given to investigational medicines that may offer major advances in treatment over available therapies.

"By providing very high cure rates in as little as eight weeks and completely eliminating the need for interferon and ribavirin, which are challenging to take and tolerate, Harvoni significantly advances treatment for patients with the most common form of hepatitis C in the United States," said Mr Nezam Afdhal, director, Hepatology at Beth Israel Deaconess Medical Center, Professor of Medicine at Harvard Medical School and a principal investigator in the Harvoni clinical trials. "For the first time, the vast majority of patients can be cured with a once-daily pill in only eight or 12 weeks."

"Unlike other serious chronic diseases, hepatitis C can be cured and Harvoni offers patients the potential for a cure in as little as eight weeks," said Dr John C Martin, chairman and chief executive officer, Gilead Sciences. "Gilead is proud to have played a role in developing a once-daily therapy that is safe, simple and well tolerated. We are now working to ensure rapid and broad access to Harvoni."