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Gilead hepatitis drug to axe treatment time by half

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Singapore: Gilead Sciences has submitted a New Drug Application (NDA) to the US FDA for approval of sofosbuvir, a once-daily oral nucleotide analogue for the treatment of chronic hepatitis C virus (HCV) infection.

The data submitted in the NDA support the use of sofosbuvir and ribavirin (RBV) as an all-oral therapy for patients with genotype 2 and 3 HCV infection, and for sofosbuvir in combination with RBV and pegylated interferon (peg-IFN) for treatment-naÃ¯ve patients with genotype 1, 4, 5 and 6 HCV infection.

Chronic HCV infection is the leading cause of liver cancer and liver transplantation in the US. Treatment for HCV currently includes 24-to-48 weeks of therapy with peg-IFN, which has to be injected and is associated with significant side effects, leaving some patients unable to complete therapy. If approved, sofosbuvir would shorten HCV therapy to 12-to-16 weeks, and depending on the genotype, would either eliminate or reduce the duration of peg-IFN injections.

Dr John C Martin, chairman and CEO, Gilead Sciences, said that, "Current therapies are not suitable for large numbers of patients with HCV infection, and are challenging to take and tolerate. Sofosbuvir's antiviral potency, safety profile and once-daily administration have the potential to improve cure rates by simplifying and shortening therapy for patients with this disease."

Gilead plans to file for regulatory approval of sofosbuvir in other geographies, including the European Union, in the second quarter of 2013.