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06 July 2015 | News | By BioSpectrum Bureau

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Tokyo: Gilead Sciences Inc. has announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) has approved 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 by the MHLW under the trade name Sovaldi in March 2015. Harvoni is indicated for the suppression of viremia in patients with genotype 1 chronic hepatitis C virus (HCV) infection with or without compensated cirrhosis, with treatment duration of 12 weeks.

Harvoni's approval in Japan is supported by data from 318 treatment-naÃ¯ve and treatment-experienced Japanese patients with genotype 1 HCV infection randomized to ledipasvir/sofosbuvir or ledipasvir/sofosbuvir plus ribavirin in the Phase 3 clinical trial GS-US-337-0113. Of the 318 patients enrolled in this study, 34 percent were ages 65 years or older and 23 percent had cirrhosis.