Japan Approves Harvoni After Study Shows 100% Cures

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Japanese regulators have approved Gilead Sciences' single-tablet combination drug Harvoni (ledipasvir/sofosbuvir) for hepatitis C virus (HCV) treatment, based on its efficacy and its ability to potentially eliminate the need for interferon and ribavirin regimens, HCP Live reports.

Japan's Ministry of Health, Labour and Welfare made the decision after Gilead submitted data showing a perfect cure rate for the drug among 380 patients in a Phase III Japanese clinical trial. The treatment has been approved for people with chronic hep C genotype 1, with or without cirrhosis.

In the study, known as GS-US-337-0113, researchers demonstrated that Harvoni treatment, taken both with and without ribavirin, cured 100 percent of treatment-naive and treatment-experienced patients after 12 weeks. Among the Harvoni-only group, side effects were notably milder than with any of the older HCV treatments.

Japanese health officials report about 70 to 80 percent of the 1 million people estimated to have hep C in Japan have genotype 1 of the virus. The country has one of the highest rates of liver cancer among industrialized nations, which experts attribute largely to HCV.

In April 2015, Gilead received approval for Sovaldi (sofosbuvir) for hep C treatment. So far, the Harvoni combo pill had only been approved for use in the United States, the European Union and Canada.

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