IN BRIEF

New Indications for Harvoni

Harvoni, a once-daily fixed-dose combination of the direct-acting antiviral agents ledipasvir and sofosbuvir approved by the FDA in 2014 for treatment of hepatitis C virus (HCV) genotype 1 infection, has now been approved for use in patients infected with HCV genotype 4, 5, or 6, and in patients co-infected with HCV and HIV-1.

A 12-week course of treatment with Harvoni plus ribavirin has also been approved as an alternative to 24 weeks of Harvoni alone for treatment-experienced, cirrhotic patients with HCV genotype 1 infection.

HCV genotypes 4, 5, and 6 are responsible for <2% of HCV cases in the US and Canada. They are more prevalent in the Middle East, North Africa, and Central sub-Saharan Africa (genotype 4), Southern sub-Saharan Africa (genotype 5), and Southeast Asia (genotype 6).

In two open-label trials (both summarized in the package insert), 44 patients infected with HCV genotype 4, 41 patients with genotype 5, and 25 patients with genotype 6 received 12 weeks of treatment with ledipasvir/sofosbuvir. The rates of sustained virologic response 12 weeks after stopping treatment (SVR12) were 93%, 93%, and 96% in patients infected with HCV genotypes 4, 5, and 6, respectively.

In a single-arm trial (ION-4), 335 patients co-infected with HIV-1 and HCV genotype 1 (98%) or 4 (2%) received 12 weeks of treatment with ledipasvir/sofosbuvir. An SVR12 was achieved in 322 patients (96%), including 94% of 67 cirrhotic patients and 97% of 185 treatment-experienced patients.

In a randomized, double-blind trial (SIRIUS), 154 treatment-experienced patients with HCV genotype 1 infection and cirrhosis who had not responded to previous protease-inhibitor therapy: a randomised, double-blind, phase 2 trial (SIRIUS). Lancet Infect Dis 2015; 15:397.