Epclusa® (sofosbuvir/velpatasvir) – Expanded indication

- On August 1, 2017, Gilead announced the FDA approval of Epclusa (sofosbuvir/velpatasvir) tablets, to include use in patients co-infected with the hepatitis C virus (HCV) and human immunodeficiency virus type 1 (HIV-1).

- Epclusa is indicated for the treatment of adult patients with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis, or with decompensated cirrhosis in combination with ribavirin.

- The expanded approval of Epclusa was supported by data from the ASTRAL-5 study, which evaluated 12 weeks of treatment with Epclusa in 106 patients with HCV/HIV co-infection and on stable HIV antiretroviral therapy.

    — Overall, 95% of patients achieved a sustained virologic response, defined as an undetectable viral load 12 weeks after completing therapy.
    — No patients had HIV rebound during treatment and CD4+ counts were stable during treatment.

- Epclusa carries a boxed warning regarding the risk of hepatitis B virus (HBV) reactivation in HCV/HBV co-infected patients.

- The safety profile of Epclusa in HCV/HIV co-infected patients was similar to that observed in HCV mono-infected patients. The most common adverse events (≥ 10%) with Epclusa use were fatigue and headache.

- The recommended dose of Epclusa is one tablet orally once daily for 12 weeks. See table below.

Patient Population	Treatment Regimen and Duration
Treatment-naïve and treatment-experienced* without cirrhosis and with compensated cirrhosis (Child-Pugh A)	Epclusa 12 weeks
Treatment-naïve and treatment-experienced* with decompensated cirrhosis (Child-Pugh B or C)	Epclusa plus ribavirin 12 weeks

* In clinical trials, regimens contained peginterferon alfa/ribavirin with or without an HCV NS3/4 protease inhibitor

    — For additional information, including dosing in other populations, refer to the Epclusa drug label.