

Gilead's Epclusa now available via the NHI scheme in Taiwan

31 May 2019 | News | By Prapti Shah

Epclusa is the first approved single tablet regimen to treat all six major genotypes of hepatitis C virus (HCV)



Gilead Sciences has announced that Epclusa (sofosbuvir 400mg/velpatasvir 100mg), a once-daily pan-genotypic, pan-fibrotic and interferon-free HCV single tablet regimen (STR) for the treatment of chronic hepatitis C, will be made available via the National Health Insurance (NHI) scheme starting on 1 June 2019.

The reimbursement of Epclusa is approved for adult patients with genotypes 1-6 HCV infection, including as a 12-week treatment for patients with or without compensated cirrhosis (Child-Pugh A) and as a 12-week treatment regimen in combination with ribavirin (RBV) for patients with decompensated cirrhosis (Child-Pugh B or C).

According to the Ministry of Health and Welfare (MoHW), there are an estimated 400,000 people living with chronic hepatitis C in Taiwan today. The MoHW has a goal of eliminating HCV nationally by 2025, five years ahead of the World Health Organization's global target for viral hepatitis elimination.

"The reimbursement of Epclusa is a significant step forward for HCV patients in Taiwan," said Pongo Peng, General Manager of Gilead Taiwan. "Gilead is committed to enabling broad access to HCV cure, in line with Taiwan's national goal to eliminate the disease."

In five international Phase 3 studies, ASTRAL-1, ASTRAL-2, ASTRAL-3, ASTRAL-4 and ASTRAL-5, Epclusa demonstrated high overall cure rates (SVR12, defined as undetectable HCV RNA 12 weeks after completing therapy), ranging from 94-100 per cent, across difficult-to-cure patient populations including treatment-experienced patients and those with compensated or decompensated cirrhosis.

The most common adverse reactions (≥ 10 per cent) experienced by patients treated with Epclusa were headache and fatigue; these events occurred at a similar frequency in placebo-treated patients. In patients with decompensated cirrhosis who were treated with Epclusa and RBV, the most common adverse reactions (≥ 10 per cent) were fatigue, anaemia, nausea, headache, diarrhoea and insomnia.

Epclusa received marketing approval from the U.S. Food and Drug Administration and the European Commission in 2016. It

is also approved for use in 54 other countries and geographies worldwide, including Taiwan.