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Singapore HSA approves Vosevi to treat Chronic Hepatitis C Virus

25 June 2019 | News

Vosevi (Sofosbuvir/ Velpatasvir/ Voxilaprevir) is the First and Only Single Tablet Regimen for patients who have previously failed therapy with Direct-Acting Antivirals

Gilead Sciences, Inc., on 24 June 2019, announced that the Singapore Health Sciences Authority (HAS) has approved Vosevi (Sofosbuvir 400mg/Velpatasvir 100mg/Voxilaprevir 100mg), a once-daily single tablet regimen for the re-treatment of adults with genotype 1-6 chronic hepatitis C virus (HCV) infection.

Vosevi is approved as a 12-week treatment regimen for patients with any genotype of chronic HCV infection, without cirrhosis, or patients with genotypes 1, 3 and 4 and compensated cirrhosis, who have previously failed therapy with a direct-acting antiviral (DAA) regimen containing NS5A inhibitor. A 12-week regimen is also approved for use in genotype 1-4 patients, without cirrhosis or with compensated cirrhosis, who had previously failed therapies containing Sofosbuvir without an NS5A inhibitor. For DAA-naïve patients with genotype 3 and compensated cirrhosis, the recommended treatment duration is 8 weeks.

Treatment with Vosevi has demonstrated high cure rates regardless of prior treatment regimens. In global, multi-centre Phase 3 clinical studies (POLARIS-1 and POLARIS 4), 96% of patients treated with Vosevi achieved the primary endpoint of SVR12, defined as maintaining undetectable viral load 12 weeks after completing therapy.

"Direct-acting antivirals have changed the course of HCV treatment, delivering high cure rates across a broad range of people living with HCV. However, certain patient populations have been more challenging to cure with previously available therapies. Vosevi now offers these patients an important new treatment option," said John McHutchison, AO, MD, Chief Scientific Officer and Head of Research and Development, Gilead Sciences.

"Gilead has developed and delivered a portfolio of HCV therapies to enable all people living with HCV to have the opportunity to be cured," said Andrew Hexter, Vice President and General Manager, Asia 5, Gilead Sciences. "Vosevi completes our portfolio of HCV therapies and is a significant step forward as we work together with health authorities, healthcare providers and the broader community toward the World Health Organization's goal of eliminating HCV by 2030."

Vosevi was approved by the U.S. Food and Drug Administration (FDA) and the European Commission in 2017.