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ASIA EDITION

CDA approves Gilead's chronic hepatitis C virus infection drug

31 May 2018 | News

HCV is the fourth-most commonly reported infectious disease in China, with approximately 10 million people infected. HCV genotypes 1, 2, 3 and 6 account for more than 96 percent of all cases.

Gilead Sciences, Inc. has announced that the China Drug Administration (CDA) has approved Epclusa for the treatment of adults with genotype 1-6 chronic hepatitis C virus (HCV) infection. The CDA also approved Epclusa in combination with ribavirin (RBV) for adults with HCV and decompensated cirrhosis. Epclusa is the first pan-genotypic HCV single tablet regimen (STR) approved in China.

The approval of Epclusa in China is supported by five international Phase 3 studies, ASTRAL-1, ASTRAL-2, ASTRAL-3, ASTRAL-4 and ASTRAL-5. High overall rates of SVR12 (defined as undetectable HCV RNA 12 weeks after completing therapy), ranging from 92-100 percent, were achieved across difficult-to-cure patient populations including treatment-experienced patients and those with compensated or decompensated cirrhosis.

"The safety and efficacy profile of Epclusa are supported by large clinical and real-world global datasets," said Professor Lai Wei, Peking University People's Hospital and Institute of Hepatology, Peking University. "With high cure rates across all HCV genotypes, Epclusa could increase HCV treatment in China by potentially eliminating the need for genotype testing, which can be a barrier to treatment in many settings."

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"As the first once-daily, interferon-free single tablet regimen for HCV patients regardless of genotype, Epclusa offers physicians in China an important new option for effectively treating their patients while potentially helping to reduce the significant burden of HCV at a population level," said John F. Milligan, PhD, Gilead's President and Chief Executive Officer. "Gilead has now launched two direct-acting antiviral treatments in China, and we are committed to supporting efforts to screen and link patients to treatment, to help address the country's HCV epidemic."

Epclusa received marketing approval from the U.S. Food and Drug Administration(FDA) and the European Commission in 2016 as the first pan-genotypic STR for HCV infection. It is also approved for use in 54 countries.

Sovaldi (sofosbuvir) as a single agent received marketing approval from the China Food and Drug Administration in 2017 for the treatment of adults infected with HCV genotype 1, 2, 3, 4, 5 or 6 and for adolescents (aged 12 to 18 years) with HCV genotype 2 or 3, as a component of a combination antiviral treatment regimen.