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Merck, known as MSD outside the United States and Canada, has announced that the US Food and Drug Administration (US FDA) has approved ZEPATIER(elbasvir and grazoprevir) for the treatment of adult patients with chronic hepatitis C virus (HCV) genotype (GT) 1 or GT4 infection, with or without ribavirin (RBV), following priority review by the FDA.

ZEPATIER is a once-daily, fixed-dose combination tablet containing the NS5A inhibitor elbasvir (50 mg) and the NS3/4A protease inhibitor grazoprevir (100 mg). The FDA previously granted two Breakthrough Therapy designations to ZEPATIER, for the treatment of chronic HCV GT1 infection in patients with end stage renal disease on hemodialysis, and for the treatment of patients with chronic HCV GT4 infection.

Across multiple clinical studies, ZEPATIER achieved high rates of sustained virologic response ranging from 94 to 97 percent in GT1-infected patients, and 97 to 100 percent in GT4-infected patients. Sustained virologic response is defined as HCV RNA levels measuring less than the lower limit of quantification at 12 weeks after the cessation of treatment (SVR12), indicating that a patient's HCV infection has been cured.

ZEPATIER is not for use in patients with moderate or severe hepatic impairment (Child-Pugh B or C). ZEPATIER also is not for use with organic anion transporting polypeptides 1B1/3 (OATP1B1/3) inhibitors (e.g., atazanavir, darunavir, lopinavir, saquinavir, tipranavir, cyclosporine), strong cytochrome P450 3A (CYP3A) inducers (e.g., carbamazepine, phenytoin, rifampin, St. John's Wort), and efavirenz. If ZEPATIER is administered with RBV, healthcare professionals should refer to the prescribing information for RBV as the contraindications, warnings and precautions, adverse reactions and dosing for RBV also apply to this combination regimen.

"Continued innovation is needed to help address the worldwide epidemic of chronic hepatitis C virus infection," said Dr Roger M Perlmutter, president, Merck Research Laboratories. "Our clinical program was designed to study a broad range of patients infected with the hepatitis C virus, including difficult-to-treat patients such as those with stage 4 or 5 chronic kidney disease.

The approval of ZEPATIER is a testament to Merck's unwavering commitment to improving therapy for patients with hepatitis C virus infection, and we are eager to bring this innovation to patients and physicians in the United States."

ZEPATIER was approved with a treatment duration of 12 or 16 weeks, depending on HCV genotype, prior treatment history and, for patients with GT1a infection, the presence of certain baseline NS5A polymorphisms. A 12-week, once-daily regimen is recommended for the vast majority of patients for whom ZEPATIER is indicated.

Merck's broad clinical trial program supporting the efficacy of ZEPATIER included six studies in 1,373 patients with chronic HCV GT1 or GT4 infection. These studies assessed the rate of sustained virologic response 12 weeks after the completion of treatment with ZEPATIER (SVR12). The clinical development program for ZEPATIER enrolled diverse groups of HCV GT1- and GT4-infected patients, including treatment-naÃ¯ve patients and those who had failed prior therapy with peginterferon alfa(PegIFN) and RBV, as well as patients suffering with meaningful co-morbidities and health complications, such as compensated cirrhosis and HIV-1 co-infection. GT1-infected patients with severe renal impairment on hemodialysis and those who previously failed therapy with PegIFN and RBV in combination with an HCV NS3/4A protease inhibitor (boceprevir, simeprevir or telaprevir) also were studied.