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Merck Discontinues MK-3682B and MK-3682C Development Programs

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Company to Focus on Maximizing the Potential of ZEPATIER ® (Elbasvir and Grazoprevir)

KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE:MRK), known as MSD outside of the United States and Canada, today announced its strategic decision to discontinue the development of the investigational combination regimens MK-3682B (grazoprevir/ruzasvir/ uprifosbuvir) and MK-3682C (ruzasvir/uprifosbuvir) for the treatment of chronic hepatitis C virus (HCV) infection. This decision was made based on a review of available Phase 2 efficacy data and in consideration of the evolving marketplace and the growing number of treatment options available for patients with chronic HCV infection, including ZEPATIER® (elbasvir and grazoprevir).

“Remarkable progress has been made in the fight against hepatitis C infection, and Merck is enormously proud of the role we have had in that fight over the past 30 years,” said Dr. Eliav Barr, senior vice president, global clinical development, infectious diseases and vaccines, Merck Research Laboratories. “We will continue to study ZEPATIER to understand even more about its role in treating chronic hepatitis C infection and will continue to work with others to help bring ZEPATIER to appropriate patients with chronic hepatitis C genotype 1 or 4 infection, the genotypes which make up the majority of patients with chronic hepatitis C infection.”

About ZEPATIER

ZEPATIER is indicated for the treatment of chronic HCV genotype (GT) 1 or 4 infection in adults. ZEPATIER is indicated for use with ribavirin in certain patient populations.

Selected Safety Information about ZEPATIER

The US Prescribing Information for ZEPATIER contains a Boxed Warning about the risk of hepatitis B virus (HBV) reactivation in patients coinfected with HCV and HBV. Healthcare professionals should test all patients for evidence of current or prior HBV infection by measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) before initiating treatment with ZEPATIER. HBV reactivation has been reported in HCV/HBV coinfected patients who were undergoing or had completed treatment with HCV direct-acting antivirals and were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death. Healthcare professionals should monitor HCV/HBV coinfected patients for clinical and laboratory signs of hepatitis flare or HBV reactivation during HCV treatment and post-treatment follow-up. Healthcare professionals should initiate appropriate patient management for HBV infection as clinically indicated.

HBV reactivation has been reported in HBsAg positive patients and also in patients with serologic evidence of resolved HBV infection (ie, HBsAg negative and anti-HBc positive). The risk of HBV reactivation may be increased in patients receiving some immunosuppressant or chemotherapeutic agents. HBV reactivation is characterized as an abrupt increase in HBV replication manifesting as a rapid increase in serum HBV DNA level. In patients with resolved HBV infection, reappearance of HBsAg can occur. Reactivation of HBV replication may be accompanied by hepatitis, ie, increases in aminotransferase levels and, in severe cases, increases in bilirubin levels, liver failure, and death can occur.

ZEPATIER (elbasvir and grazoprevir) is not for use in patients with moderate or severe hepatic impairment (Child Pugh B or C). ZEPATIER is also not for use with inhibitors of organic anion transporting polypeptides 1B1/3 (OATP1B1/3) that are known or expected to significantly increase grazoprevir plasma concentrations (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 (elbasvir and grazoprevir) 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.

Elevations of alanine transaminase (ALT) to greater than 5 times the upper limit of normal (ULN) occurred in 1% of subjects, generally at or after treatment week 8. These late ALT elevations were typically asymptomatic and most resolved with ongoing or completion of therapy. Healthcare professionals should perform hepatic lab testing on patients prior to therapy, at treatment week 8, and as clinically indicated. For patients receiving 16 weeks of therapy, additional hepatic lab testing should be performed at treatment week 12.

Patients should be instructed to consult their healthcare professional without delay if they have onset of fatigue, weakness, lack of appetite, nausea and vomiting, jaundice or discolored feces. Healthcare providers should consider discontinuing ZEPATIER (elbasvir and grazoprevir) if ALT levels remain persistently greater than 10 times ULN. ZEPATIER should be discontinued if ALT elevation is accompanied by signs or symptoms of liver inflammation or increasing conjugated bilirubin, alkaline phosphatase, or international normalized ratio.

The concomitant use of ZEPATIER with certain drugs may lead to adverse reactions or reduced therapeutic effect due to drug interactions. Certain strong CYP3A inhibitors may increase the plasma concentration of ZEPATIER, leading to possibly clinically significant adverse reactions. Moderate CYP3A inducers may decrease the plasma concentration of ZEPATIER, leading to reduced therapeutic effect and possible development of resistance. Coadministration of ZEPATIER with these drugs is not recommended. Physicians should consult the Prescribing Information for potential drug interactions.

In subjects receiving ZEPATIER for 12 weeks, the most commonly reported adverse reactions of all intensity (greater than or equal to 5% in placebo-controlled trials) were fatigue, headache and nausea. In subjects receiving ZEPATIER with RBV for 16 weeks, the most commonly reported adverse reactions of moderate or severe intensity (greater than or equal to 5%) were anemia and headache.

Selected Dosage and Administration Information for ZEPATIER ® (elbasvir and grazoprevir) 50 mg/100mg tablets

ZEPATIER is a single tablet taken once daily. The recommended dosing is 12 or 16 weeks with or without RBV, depending on HCV genotype, prior treatment history and, for patients with genotype 1a infection, presence of certain baseline NS5A resistance-associated polymorphisms. See Prescribing Information for ZEPATIER for specific dosage regimens and durations. Refer to RBV prescribing information for RBV dosing and dosage modifications when ZEPATIER is given with RBV. To determine dosage regimen and duration of ZEPATIER for genotype 1a patients, testing for the presence of virus with one or more baseline NS5A resistance-associated polymorphisms at positions 28, 30, 31, or 93 is recommended prior to initiating treatment.

About Merck

For more than a century, Merck, a leading global biopharmaceutical company known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world - including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer's disease and infectious diseases including HIV and Ebola. For more information, visit www.merck.com and connect with us on Twitter, Facebook, Instagram, YouTube and LinkedIn.

Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's 2016 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

Please see Prescribing Information for ZEPATIER (elbasvir and grazoprevir), including the Boxed Warning about the risk of HBV reactivation in patients coinfected with HCV and HBV, at http://www.merck.com/product/usa/pi_circulars/z/zepatier/zepatier_pi.pdf and Patient Information for ZEPATIER at http://www.merck.com/product/usa/pi_circulars/z/zepatier/zepatier_ppi.pdf

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