Merck to Present New Data on ZEPATIER® (elbasvir and grazoprevir) and Investigational Combination Therapy MK-3682B for the Treatment of Chronic Hepatitis C Infection at The International Liver Congress™ 2017

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KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE:MRK), known as MSD outside of the United States and Canada, today announced that new data from the company’s chronic hepatitis C virus (HCV) clinical development programs as well as real-world studies on ZEPATIER® (elbasvir and grazoprevir) 50mg/100mg tablets will be presented at the upcoming International Liver Congress™ 2017. Seventeen scientific abstracts will be presented, including oral sessions featuring real-world data on chronic HCV-infected patients treated with ZEPATIER from the U.S. Department of Veterans Affairs Healthcare System and new results from the C-SURGE trial evaluating MK-3682B [uprifosbuvir (MK-3682)1/grazoprevir2/nuazavir3] in patients with chronic HCV infection who have previously failed a HCV direct-acting antiviral regimen. The International Liver Congress™ 2017 will take place in Amsterdam, Netherlands from April 19 – 23, 2017.

“We continue to generate new data on ZEPATIER while advancing our ongoing investigational program evaluating uprifosbuvir in combination with other assets, underscoring our continued commitment to chronic HCV research,” said Dr. Eliav Barr, senior vice president, global clinical development, infectious diseases and vaccines, Merck Research Laboratories. “Findings from both randomized clinical trials and real-world data analyses help us better understand the treatment of diverse patient types, including those who have been historically underserved or for whom unmet needs remain.”

In the United States, ZEPATIER is indicated for the treatment of chronic HCV genotype (GT) 1 or GT4 infection in adults. ZEPATIER is indicated for use with ribavirin (RBV) in certain patient populations. The U.S. Prescribing Information for ZEPATIER contains a Boxed Warning about the risk of hepatitis B virus (HBV) reactivation in patients co-infected with HCV and HBV.

Key presentations at The International Liver Congress™ 2017 will include:

**ZEPATIER (elbasvir and grazoprevir)**

Thursday, April 20

- Real-World Use of Elbasvir/Grazoprevir and Outcomes in Patients With Chronic Hepatitis C: Retrospective Data Analyses From the TRIO Network (Poster presentation, Abstract THU-239, 8:00 a.m. – 6:00 p.m. CEST)
- Prevention of Liver-Related Complications With Elbasvir/Grazoprevir in Hepatitis C Infected Patients who are Receiving Opioid Agonist Therapy (OAT) (Poster presentation, Abstract THU-246, 8:00 a.m. – 6:00 p.m. CEST)
- Real-World Utilization of the New Fixed-Dose Combination Elbasvir/Grazoprevir in Adult Patients With Chronic Hepatitis C in Canada: Z-PROFILE Study (Poster presentation, Abstract THU-266, 8:00 a.m. – 6:00 p.m. CEST)
- Clinically Meaningful Differences in Health-Related Quality of Life and Fatigue in Patients With Hepatitis C Virus (HCV) Infection Treated With Elbasvir/Grazoprevir (EBR/GZR) Compared to Sofosbuvir (SOF) With Pegylated Interferon and Ribavirin (PR) (Poster presentation, Abstract THU-245, 8:00 a.m. – 6:00 p.m. CEST)
- Projected Long Term Impact of Elbasvir/Grazoprevir (EBR/GZR) Compared to Sofosbuvir Plus Pegylated Interferon/Ribavirin (SOF+PR) in Chronic Hepatitis C Virus Genotype 1 and 4 Patients in Italy: Translation of the C-EDGE Head-2-Head Study Findings (Poster presentation, Abstract THU-247, 8:00 a.m. – 6:00 p.m. CEST)
- Safety and Efficacy of Elbasvir and Grazoprevir With or Without Ribavirin for the Treatment of Hepatitis C Virus Genotype 1: Results of the Hepatitis C Virus-TARGET Study (Poster presentation, Abstract THU-237, 8:00 a.m. – 6:00 p.m. CEST)

Friday, April 21

- Real World Experience With Elbasvir/Grazoprevir in the Veterans Affairs Healthcare System (Oral presentation, Abstract PS-095, 4:00 – 4:15 p.m. CEST)
MK-3682B, INVESTIGATIONAL TRIPLE THERAPY

Saturday, April 22

Elbasvir/Grazoprevir Effectiveness in Patients With Chronic Hepatitis C and Chronic Kidney Disease: Real-World Experience From the Trio Network (Poster presentation, Abstract SAT-297, 8:00 a.m. – 6:00 p.m. CEST)

Elbasvir/Grazoprevir Plus Sofosbuvir in Treatment-Naive and Treatment-Experienced Cirrhotic Patients With Hepatitis C Virus Genotype 3 Infection Treated for 8, 12, or 16 weeks: Final Results of the C-ISLE Study (Poster presentation, Abstract FRI-213, 8:00 a.m. – 6:00 p.m. CEST)

Successful Treatment of Patients With HCV GT3 Infection and Cirrhosis with Elbasvir/Grazoprevir Plus Sofosbuvir Does Not Correct Insulin Resistance by 12 weeks Post-Treatment (Poster presentation, Abstract FRI-215, 8:00 a.m. – 6:00 p.m. CEST)

Impact of Elbasvir/Grazoprevir (EBR/GZR) on Health-Related Quality of Life (HRQOL) and Fatigue in Patients With Chronic Hepatitis C Virus (HCV) Infection and Inherited Blood Disorders (IBLD): Data From the C-EDGE IBLDS Study (Poster presentation, Abstract FRI-251, 8:00 a.m. – 6:00 p.m. CEST)

周六, April 22

Elbasvir/Grazoprevir® (elbasvir and grazoprevir) 50mg/100mg Tablets

ZEPATIER® (elbasvir and grazoprevir) is a fixed-dose combination product containing elbasvir, a HCV NS5A inhibitor, and grazoprevir, an HCV NS3/4A protease inhibitor. In the United States, ZEPATIER is indicated for the treatment of chronic HCV GT1 or 4 infection in adults. ZEPATIER is indicated for use with ribavirin (RBV) in certain patient populations. ZEPATIER is not indicated to treat chronic HCV GT3 or GT6 infection. ZEPATIER has been approved in over 17 countries worldwide, including the United States, Canada, the European Union, Switzerland, Israel, Saudi Arabia, Australia, Japan, Vietnam, Georgia, Korea, New Zealand, Mexico, Taiwan, Egypt, Bahrain, and Argentina, with additional regulatory approvals anticipated.

Selected Safety Information about ZEPATIER

The U.S. 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 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, death, 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 (i.e., HBsAg negative and anti-HBc positive). The risk of HBV reactivation may be increased in patients receiving some immunosuppressive 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, i.e., increases in aminotransferase levels and, in severe cases, increases in bilirubin levels, liver failure, and death can occur.

ZEPATIER 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.

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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 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)

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.

Merck’s Commitment to HCV

For more than 30 years, Merck has been at the forefront of the response to the HCV epidemic. Merck’s chronic HCV clinical development programs have included more than 135 clinical trials in approximately 40 countries and have enrolled nearly 10,000 participants. As part of our longstanding leadership in infectious diseases, Merck collaborates with the scientific and patient communities to develop and deliver innovative solutions to support people living with chronic HCV worldwide.

About Merck

For 125 years, Merck has been a global health care leader working to help the world be well. Merck is known as MSD outside the United States and Canada. 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. For more information, visit www.merck.com and connect with us on Twitter, Facebook, 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).


1 MK-3682 is an HCV nucleotide analogue NS5B polymerase inhibitor.
2 Grazoprevir is an HCV NS3/4A protease inhibitor (100mg).
3 Rusazvir (MK-8408) is an HCV NS5A inhibitor.
English

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