Merck to Present New Data on ZEPATIER® (elbasvir and grazoprevir) for the Treatment of Chronic Hepatitis C Virus Infection at The Liver Meeting® 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 data from the company’s chronic hepatitis C clinical development programs and real-world studies are scheduled to be presented at The Liver Meeting® 2017. These data presentations include new analyses of ZEPATIER® (elbasvir and grazoprevir) in real-world settings and follow-up analyses from Phase 3 clinical trials, including findings from the C-EDGE CO-STAR three-year observational follow-up study evaluating chronic hepatitis C virus (HCV) reinfection incidence and risk behaviors in patients who were treated with ZEPATIER while on opioid agonist therapy (OAT). The Liver Meeting® 2017 will take place in Washington, D.C., from Oct. 20-24, 2017.

"Merck has been a leader in chronic hepatitis C for more than 30 years. Now, with the availability of treatments such as ZEPATIER, we believe our focus needs to be on understanding its application in the real world," said Dr. Michael Robertson, executive director of clinical research, Merck Research Laboratories. "Analysis of data from patients treated with ZEPATIER around the world provides important insights that may help inform elimination efforts, particularly among difficult-to-treat populations."

In the United States, 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. 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.

Key presentations at The Liver Meeting® 2017 will include:

ZEPATIER ® (elbasvir and grazoprevir) 50mg/100mg tablets

Saturday, October 21

- Effectiveness of Elbasvir/Grazoprevir in Patients With Chronic Hepatitis C and Chronic Kidney Disease: Results From the Veterans Affairs System (Poster presentation, Abstract 1113, 2:00 p.m. – 7:30 p.m. EDT)
- A Pragmatic Approach to Optimizing the Efficacy of Elbasvir/Grazoprevir Using Baseline Viral Load in Participants With Hepatitis C Virus (HCV) Genotype (GT)1a Infection: A Post Hoc Analysis of 11 Clinical Trials (Poster presentation, Abstract 1124, 2:00 p.m. – 7:30 p.m. EDT)
- Impact of Treatment Duration and Ribavirin (RBV) Addition on Real-World Effectiveness of Elbasvir/Grazoprevir (EBR/GZR) in Select Patient Subgroups With Genotype 1 (GT1) Chronic Hepatitis C (HCV): Retrospective Data Analyses From the Trio Network. (Poster presentation, Abstract 1128, 2:00 p.m. – 7:30 p.m. EDT)
- Real-World Cost-Effectiveness of Elbasvir/Grazoprevir (EBR/GZR) in Treatment-Naïve (TN) Patients With Chronic Hepatitis C (CHC) Virus Genotype 1 (GT1) in the United States (US) (Poster presentation, Abstract 1155, 2:00 p.m. – 7:30 p.m. EDT)

Sunday, October 22

- Safety and Efficacy of Elbasvir/Grazoprevir in Asian Participants With Hepatitis C Virus Genotypes 1 and 4 Infection: An Integrated Analysis of Data From 11 Phase 2/3 Trials (Poster presentation Abstract 1522, 8:00 a.m. – 5:30 p.m. EDT)
- Co-Morbidities and Clinically Relevant Drug-Drug Interactions (DDIs) in Patients Undergoing Treatment of Chronic HCV Genotype 1 (GT1) Infection With Elbasvir (EBR)/Grazoprevir (GZR): Results From the German Hepatitis C Registry (DHC-R) (Poster presentation, Abstract 1546, 8:00 a.m. – 5:30 p.m. EDT)
- Utilization and Effectiveness of Elbasvir/Grazoprevir (EBR/GZR) in Treatment Naive (TN) Genotype 1a (G1a) Chronic Hepatitis C Virus (HCV) Patients With/Without Baseline NSSA Resistance-Associated Substitutions (RASs) (Poster presentation, Abstract 1568, 8:00 a.m. – 5:30 p.m. EDT)
- Safety and Efficacy of Elbasvir (EBR)/Grazoprevir (GZR) in Hepatitis C Virus (HCV) GT1- and GT4-infected Participants 65 Years and Older: An Integrated Analysis of Twelve Clinical Trials (Poster presentation, Abstract 1589, 8:00 a.m. –
Monday, October 23

- Hepatitis C Virus (HCV) Reinfection and Injecting Risk Behavior Following Elbasvir (EBR)/Grazoprevir (GZR) Treatment in Participants on Opiate Agonist Therapy: Co-STAR Part B (Oral presentation, Abstract 195, 3:30 p.m. – 3:45 p.m. EDT)

ADDITIONAL STUDIES OF NOTE

Saturday, October 21

- Epidemiologic Impact of Expanding Chronic Hepatitis C (CHC) Treatment in People who Inject Drug (PWID) in the United States (US): A Mathematical Model Using Data From the C-EDGE CO-STAR Study (Poster presentation, Abstract 976, 2:00 p.m. – 7:30 p.m. EDT)
- Economic Burden of Chronic Hepatitis C (CHC) in Medicaid and Commercially Insured Patients in the United States (Poster presentation, Abstract 1008, 2:00 p.m. – 7:30 p.m. EDT)
- Perceived Barriers Related to the Management of HCV Infection Among Physicians Prescribing Opioid Agonist Therapy: The C-SCOPE Study (Poster presentation, Abstract 1064, 2:00 p.m. – 7:30 p.m. EDT)

For more information, including a complete list of abstract titles at the meeting, please visit: http://www.aasld.org/events-professional-development/liver-meeting

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)

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 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).


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English

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