Merck to Present New Findings from Chronic Hepatitis C Clinical Development Programs at The International Liver Congress™ 2016

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Presentations Include Results from Phase 3 Study Evaluating ZEPATIER™ (elbasvir and grazoprevir) Compared to Sofosbuvir-Containing Regimen, and Results from Studies in Difficult-to-Treat Populations

KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE:MRK), known as MSD outside of the United States and Canada, today announced the planned presentations of data from the company’s broad chronic hepatitis C virus (HCV) clinical development programs at the upcoming International Liver Congress™ 2016. Clinical data from trials evaluating ZEPATIER™ (elbasvir and grazoprevir) 50mg/100mg tablets will be featured, including the Phase 3 C-EDGE Head-to-Head trial comparing ZEPATIER to a regimen of sofosbuvir with peginterferon alfa and ribavirin (RBV), and the Phase 3 C-EDGE IBLD and C-EDGE CO-STAR studies evaluating ZEPATIER in underserved patients with historically difficult-to-treat conditions. In addition, data from trials evaluating Merck’s chronic HCV candidates MK-3682B (grazoprevir/MK-84081/MK-36822) and MK-8408 monotherapy will be presented. ZEPATIER – Merck’s once-daily, fixed-dose combination tablet indicated with or without RBV for the treatment of chronic HCV genotype (GT) 1 or GT4 infection in adults – was approved by the U.S. Food and Drug Administration (FDA) on Jan. 28, 2016. The International Liver Congress™ 2016 is scheduled to take place at the Fira Barcelona Gran Via, Barcelona, Spain from April 13-17, 2016.

“We continue to build on the data that supported the recent U.S. FDA approval of ZEPATIER with additional studies that provide clinical evidence about ZEPATIER in multiple patient populations,” said Dr. Eliav Barr, vice president, infectious diseases, Merck Research Laboratories. “Merck remains committed to the fight against chronic hepatitis C through our ongoing clinical programs exploring diverse patient groups and areas of unmet need.”
At The International Liver Congress™ 2016, key data presentations will include:

- New data from the Phase 3 C-EDGE clinical trial program, evaluating ZEPATIER (elbasvir and grazoprevir) (with or without RBV), across multiple HCV genotypes (1, 4 and 6) and diverse patient populations, including those who are historically difficult-to-treat, over a 12-week treatment duration.

Thursday, April 14:

- **C-EDGE Head-to-Head (H2H):** Efficacy and Safety of Elbasvir and Grazoprevir Compared With Sofosbuvir/Pegylated Interferon/Ribavirin: A Phase 3 Randomized Controlled Trial (Oral presentation, Abstract #PS002, 4:15 p.m.-4:30 p.m. CEST)
- **C-EDGE CO-STAR:** Favorable Impact of Elbasvir and Grazoprevir on Health-Related Quality of Life in Treatment-Naïve HCV-Infected Persons Who Inject Drugs Receiving Opioid Agonist Therapy (Poster presentation, Abstract #THU-225, 8:00 a.m.-6:00 p.m. CEST)

Saturday, April 16:

- **C-EDGE IBLD:** Efficacy and Safety of Elbasvir/Grazoprevir (EBR/GZR) in Subjects With Chronic Hepatitis C Virus Infection and Inherited Blood Disorders (IBLD) (Poster presentation, Abstract #SAT-128, 8:00 a.m.-6:00 p.m. CEST)
- **C-EDGE TN:** Final SVR24 Data From the Phase 3 C-EDGE Treatment-Naïve (TN) Study of Elbasvir (EBR)/Grazoprevir (GZR) in Patients With Chronic HCV Genotype 1, 4 or 6 Infection (Poster presentation, Abstract #SAT-266, 8:00 a.m.-6:00 p.m. CEST)
- **C-EDGE CO-STAR:** Risk of Reinfection Following Successful Therapy With Elbasvir and Grazoprevir in Persons Who Inject Drugs (PWID) Receiving Opioid Agonist Therapy (OAT) (Poster presentation, Abstract #SAT-163, 8:00 a.m.-6:00 p.m. CEST)

**Additional Presentations of Interest**

Thursday, April 14:

- In a 5-Day Monotherapy Trial, MK-8408 Demonstrates Potent Antiviral Activity and Improved Resistance Profile in HCV Patients With Genotypes 1, 2, and 3 Infections (Poster presentation, Abstract #THU-222, 8:00 a.m.-6:00 p.m. CEST)

Saturday, April 16:

- High Efficacy of an 8-Week 3-Drug Regimen of Grazoprevir/MK-8408/MK-3682 in HCV Genotype 1, 2 and 3-
Infected Patients: SVR24 Data From the Phase 2 C-CREST 1 and 2 Studies (Poster presentation, Abstract #SAT-139, 8:00 a.m.-6:00 p.m. CEST)

- **C-SWIFT** Retreatment Final Results: Highly Successful Retreatment of GT1-Infected Patients With 12 Weeks of Elbasvir/Grazoprevir Plus Sofosbuvir and Ribavirin After Failure of Short-Duration All-Oral Therapy (Poster presentation, Abstract #SAT-148, 8:00 a.m.-6:00 p.m. CEST)

- Cost Effectiveness of Elbasvir (EBS, MK-8742)/Grazoprevir (GZR/MK-5172) Use in Treatment-Naïve and Treatment-Experienced Patients With Hepatitis C Virus (HCV) Genotype 1 Infection and Chronic Kidney Disease (CKD) in the United States (Poster presentation, Abstract #SAT-141, 8:00 a.m.-6:00 p.m. CEST)

- Sustained Virologic Response Among Patients With Genotype 1 Hepatitis C and Treated With Interferon-Free Direct-Acting Antiviral Regimens (Poster presentation, Abstract #SAT-217, 8:00 a.m.-6:00 p.m. CEST)

- Characteristics and Prevalence of Chronic Kidney Disease Among Patients With Hepatitis C Who Are Treated With Interferon-Free Direct-Acting Antiviral Regimens (Poster presentation, Abstract #SAT-109, 8:00 a.m.-6:00 p.m. CEST)

For more information, including a complete list of abstract titles at the meeting, please visit: [http://ilc-congress.eu/](http://ilc-congress.eu/).

**Selected Safety Information about ZEPATIER (elbasvir and grazoprevir)**

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 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 (elbasvir and grazoprevir) is administered with ribavirin (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 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 possible clinically significant adverse reactions from greater exposure to ZEPATIER or concomitant drugs. Coadministration of ZEPATIER is not recommended with certain strong CYP3A inhibitors (e.g., ketoconazole or the cobicistat-containing regimens of elvitegravir/cobicistat/emtricitabine/tenofovir [disoproxil fumarate or alafenamide]). Healthcare professionals should not exceed atorvastatin 20mg/daily or rosuvastatin 10mg/daily when given with ZEPATIER. If ZEPATIER is given with fluvastatin, lovastatin or simvastatin, healthcare professionals should give the lowest statin dose necessary and closely monitor for statin-associated adverse events. If ZEPATIER and tacrolimus are coadministered, frequent monitoring of tacrolimus whole blood concentrations, changes in renal function and tacrolimus-associated adverse events is recommended.

The concomitant use of ZEPATIER and certain drugs may cause significant decrease of elbasvir and grazoprevir plasma concentrations, which may lead to reduced therapeutic effect of ZEPATIER and possible development of resistance. Coadministration of ZEPATIER is not recommended with moderate CYP3A inducers (e.g., nafcillin, bosentan, etravirine, modafinil).

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.

About ZEPATIER™ (elbasvir and grazoprevir) 50mg/100mg Tablets

ZEPATIER is a fixed-dose combination product containing elbasvir, a hepatitis C virus (HCV) NS5A inhibitor, and grazoprevir, an HCV NS3/4A protease inhibitor, and is indicated with or without ribavirin (RBV) for treatment of chronic HCV genotype (GT) 1 or GT4 infection in adults. The dosing regimens and durations for treatment with once-daily ZEPATIER for chronic HCV GT1 or GT4 infection in patients with or without cirrhosis, HIV-1 co-infection or renal impairment are as follows:

- Twelve weeks of treatment with ZEPATIER is recommended for: GT1a-infected patients who are treatment-naïve or who failed prior treatment with peginterferon alfa plus RBV (PegIFN/RBV-experienced) without baseline NS5A resistance-associated polymorphisms (amino acid positions 28, 30, 31 or 93); GT1b-infected patients who are treatment-naïve or PegIFN/RBV-experienced; and GT4-infected patients who are treatment-naïve.
- Twelve weeks of treatment with ZEPATIER in combination with RBV is recommended for GT1a- or GT1b-infected patients who failed prior treatment with PegIFN/RBV + a HCV NS3/4A protease inhibitor (PI) (boceprevir, simeprevir or telaprevir). For GT1a-infected PegIFN/RBV/PI-experienced patients with one or
more baseline NS5A resistance-associated polymorphisms, the optimal ZEPATIER-based treatment regimen and duration of therapy has not been established.

- Sixteen weeks of treatment with ZEPATIER in combination with RBV is recommended for: GT1a-infected patients who are treatment-naïve or PegIFN/RBV-experienced with baseline NS5A resistance-associated polymorphisms; and GT4-infected patients who are PegIFN/RBV-experienced.

For patients with chronic HCV GT1a infection, testing for the presence of NS5A resistance-associated polymorphisms is recommended prior to starting treatment with ZEPATIER to determine the optimal dosage regimen and duration.

Merck’s Commitment to HCV

For nearly 30 years, Merck has been at the forefront of the response to the HCV epidemic. Merck employees are dedicated to applying their scientific expertise, resources and global reach to develop and deliver innovative healthcare 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 2015 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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1 MK-8408 is an HCV NS5A inhibitor

2 MK-3682 is an HCV nucleotide analogue NS5B polymerase inhibitor

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