NEWS RELEASE

Merck to Release Findings from Integrated Analysis of Six Phase 2 and 3 Clinical Trials Evaluating Investigational Elbasvir/Grazoprevir in Patients with Chronic Hepatitis C Genotype 1, 4 or 6 Infection and Compensated Cirrhosis at The Liver Meeting®

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Patients with Compensated Liver Cirrhosis Among Most Difficult-to-Treat

KENILWORTH, N.J.--(**BUSINESS WIRE**)--Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced the presentation of results from an integrated analysis of patients with compensated liver cirrhosis (Child-Pugh class A) from six Phase 2 and 3 clinical trials evaluating the efficacy and safety of the investigational once-daily tablet elbasvir/grazoprevir1 (50mg/100mg) with or without ribavirin (RBV) in patients with chronic hepatitis C virus (HCV) genotypes (GT) 1, 4 or 6 infection. Results from the full analysis set (FAS) (n=402) demonstrate that treatment-naïve patients with compensated liver cirrhosis who received elbasvir/grazoprevir with or without RBV for 12 weeks achieved sustained virologic response 12 weeks after the completion of treatment (SVR12, or virologic cure) at rates of 90 percent (28/31) and 98 percent (135/138), respectively. Treatment-experienced patients who received elbasvir/grazoprevir with or without RBV for 12 weeks achieved virologic cure rates of 91 percent (74/81) and 89 percent (48/54), respectively. Treatment-experienced patients who received elbasvir/grazoprevir with or without RBV for 16 or 18 weeks achieved virologic cure rates of 100 percent (49/49) and 94 percent (46/49), respectively. These data will be presented during an oral presentation at **The Liver Meeting®** (Abstract #42).

“Patients with chronic hepatitis C virus infection and compensated cirrhosis have historically been difficult to treat

because their bodies' ability to respond to antiviral therapy is compromised," said Dr. Ira Jacobson, site chair, department of medicine, Mount Sinai Beth Israel, New York. "In this integrated analysis of data from multiple trials, patients treated with elbasvir/grazoprevir were able to achieve high virologic cure rates, often without the addition of ribavirin."

The integrated analysis included patients with compensated liver cirrhosis (Child-Pugh class A) from six Phase 2 and 3 clinical trials, the individual results of which have been previously presented: **C-WORTHy**, **C-SURFER**, **C-EDGE TN**, **C-EDGE CO-INXFN**, **C-EDGE TE** and **C-SALVAGE**. The analysis evaluated the efficacy and safety of investigational once-daily elbasvir/grazoprevir with or without RBV for 12 weeks in treatment-naïve patients (n=169) and 12 and 16 or 18 weeks in treatment-experienced patients (n=233). Of the treatment-experienced patients, 64 percent (150/233) were prior non-responders, 21 percent (49/233) were prior relapsers and 15 percent (34/233) were previously treated with HCV NS3/4A protease inhibitors (simeprevir, telaprevir and boceprevir).

Two sets of patients were analyzed. In the FAS, the assessment included all randomized patients who received at least one dose of drug (n=402). The integrated analysis also assessed a modified full analysis set (mFAS) (n=398) that excluded four patients who discontinued treatment for reasons unrelated to the study drug: one treatment-naïve patient on 12 weeks of elbasvir/grazoprevir without RBV; two treatment-experienced patients on 12 weeks of elbasvir/grazoprevir without RBV; and one treatment-experienced patient on 12 weeks of elbasvir/grazoprevir with RBV. Compensated cirrhosis was determined by one of the following methods: liver biopsy, FibroScan, AST to platelet ratio or FibroTest.

Summary of SVR12 Findings: FAS

Table 1

	Treatment-Naïve		Treatment-Experienced			
	Without RBV (n=138)	With RBV (n=31)	Without RBV (n=54)	With RBV (n=81)	Without RBV (n=49)	With RBV (n=49)
Duration (Weeks)	12	12	12	12	16 or 18	16 or 18
All Patients	98% (135/138)*	90% (28/31)†	89% (48/54)§	91% (74/81)‡	94% (46/49)#	100% (49/49)

* Virologic failure occurred in one percent (2/138) of patients including one breakthrough and one relapse.

† Virologic failure occurred in 10 percent (3/31) of patients including one breakthrough and two relapses.

§ Virologic failure occurred in seven percent (4/54) of patients including four relapses.

‡ Virologic failure occurred in seven percent (6/81) of patients including six relapses.

Virologic failure occurred in six percent (3/49) of patients including two rebounds and one relapse.

Summary of SVR12 Findings: mFAS2

Table 2a

	Treatment-Naïve Without RBV (n=137)*			
Duration (Weeks)	12			
All Patients	99% (135/137)**			
Genotype	GT1a	GT1b	GT4	GT6
	97% (73/75)	100% (56/56)	100% (6/6)	-

* In the additional population of treatment naïve patients administered elbasvir/grazoprevir with RBV for 12 weeks, 90% (28/31) achieved SVR12.

** Virologic failure occurred in one percent (2/137) of patients including one breakthrough and one relapse.

Table 2b

	Treatment-Experienced† Without RBV (n=52)*			With RBV (n=49)**		
Duration (Weeks)	12			16 or 18		
All Patients	92% (48/52)***			100% (49/49)		
Genotype	GT1	GT4	GT6	GT1	GT4	GT6
	94% (44/47)	80% (4/5)	-	100% (44/44)	100% (4/4)	100% (1/1)

† Prior null response, partial response or relapse with pegylated interferon/RBV

* In the additional population of treatment-experienced patients administered elbasvir/grazoprevir with RBV for 12 weeks, 93% (74/80) achieved SVR12.

** In the additional population of treatment-experienced patients administered elbasvir/grazoprevir without RBV for 16 or 18 weeks, 94% (46/49) achieved SVR12.

*** Virologic failure occurred in eight percent (4/52) of patients including four relapses.

The most common adverse events (AEs) reported in patients who received elbasvir/grazoprevir, or elbasvir/grazoprevir with RBV, and placebo were: fatigue (15%, 31% and 18%, respectively), headache (17%, 21% and 14%, respectively) and nausea (4%, 14% and 14%, respectively). One serious drug-related AE occurred in a patient taking elbasvir/grazoprevir due to severe abdominal pain without associated symptoms. Seven patients discontinued due to treatment-related AEs (two patients taking elbasvir/grazoprevir; four patients taking elbasvir/grazoprevir with RBV; and one patient taking placebo).

About Elbasvir/Grazoprevir

Elbasvir/grazoprevir is Merck's investigational, once-daily, fixed-dose combination therapy containing elbasvir (HCV NS5A replication complex inhibitor) and grazoprevir (HCV NS3/4A protease inhibitor). Merck's broad clinical trials program includes evaluations of elbasvir/grazoprevir with or without ribavirin for multiple HCV genotypes, together with patients with difficult-to-treat conditions, such as cirrhosis, advanced chronic kidney disease, HIV/HCV co-infection, inherited blood disorders and those on opioid agonist therapy. In July 2015, the U.S. Food and Drug Administration (FDA) granted Priority Review for the New Drug Application for elbasvir/grazoprevir with a Prescription Drug User Fee Act (PDUFA) action date of Jan. 28, 2016.

In April 2015, the FDA granted Breakthrough Therapy Designation for elbasvir/grazoprevir for the treatment of patients with chronic HCV GT1 infection with end stage renal disease on hemodialysis, and Breakthrough Therapy Designation for elbasvir/grazoprevir for the treatment of patients with chronic HCV GT4 infection. Breakthrough Therapy Designation is intended to expedite the development and review of a candidate that is planned for use, alone or in combination, to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

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 deliver innovative healthcare solutions that support people living with HCV worldwide.

About Merck

Today's Merck is 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 2014 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 Elbasvir is an HCV NS5A replication complex inhibitor and grazoprevir is an HCV NS3/4A protease inhibitor.

2 Data presented in Tables 2a and 2b include regimens by treatment population with the highest rates of SVR or comparable SVR without the addition of RBV.

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