



NEWS RELEASE

Merck Announces Presentation of Phase 2 Clinical Trial Results of Investigational Chronic Hepatitis C Therapy Grazoprevir/Elbasvir at the International Liver Congress™ 2015

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Results of C-SALVAGE Study Showed High Sustained Virologic Response Rates in Patients Who Failed Prior Combination Therapy with Certain Direct Acting Antiviral (DAA) Agents

Results of C-SWIFT Study Provide Proof-of-Concept for Shorter Than Twelve Weeks Duration of Treatment with Triple-DAA Regimen in Patients with Chronic Hepatitis C Virus (HCV) Genotypes 1 and 3 Infection

KENILWORTH, N.J. – April 25, 2015 – Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced the presentation of results from two Phase 2 clinical trials evaluating the safety and efficacy of the company's investigational once-daily treatment regimen of grazoprevir (100mg) and elbasvir (50mg)[1] in adult patients with chronic hepatitis C virus (HCV) infection. Treatment with grazoprevir and elbasvir in combination with ribavirin (RBV) (C-SALVAGE trial) showed high rates of sustained virologic response 12 weeks after the completion of treatment (SVR12) in patients with chronic HCV genotype 1 (GT1) infection with or without liver cirrhosis who previously failed combination therapy with a DAA agent. In addition, final results from the C-SWIFT study evaluating grazoprevir/elbasvir in combination with sofosbuvir 400mg in treatment-naïve patients with or without liver cirrhosis chronically infected with HCV GT1 or GT3 were presented as proof-of-concept for potentially shortening HCV treatment duration below 12 weeks. Data from these studies were presented at **The International Liver Congress™ 2015** – the 50th annual congress of the European Association for the Study of the Liver. "We continue to advance our Phase 3 clinical program for grazoprevir/elbasvir evaluating diverse patient populations with chronic



HCV infection, including those widely considered among the most difficult to treat,” said Dr. Eliav Barr, vice president, infectious diseases, Merck Research Laboratories. “Findings from these Phase 2 studies formed part of the basis for our decision to rapidly advance our large and comprehensive clinical development program that incorporates studies dedicated to patient populations with specific unmet medical needs.”

C-SALVAGE Overview and Findings

C-SALVAGE (Abstract #O001) is a Phase 2, single arm, open label clinical trial conducted to evaluate the efficacy and safety of 12 weeks of treatment with grazoprevir and elbasvir plus RBV in patients with chronic HCV GT1 infection who have previously failed treatment with peginterferon and RBV combined with a DAA (boceprevir, simeprevir or telaprevir). Of the 79 patients who received one or more doses of grazoprevir and elbasvir, 43 percent had liver cirrhosis.

Following 12 weeks of treatment with a combination of grazoprevir and elbasvir plus RBV, 96 percent of the patients (76/79) with chronic HCV GT1 infection who had failed prior treatment with specified DAA-based regimens achieved SVR12. Ninety four percent (32/34) of patients with compensated cirrhosis achieved SVR12. Virologic failure was reported for three patients in the trial. All three patients had resistance associated variants at baseline and relapsed after completion of study treatment.

The most common adverse events included fatigue (28%), headache (19%), asthenia (15%) and nausea (12%). Five serious adverse events were reported, none of which were considered related to study drug. One patient discontinued treatment due to an adverse event that was not considered to be drug-related. Detailed findings of the study were recently posted online in the “Articles in Press” section of the **Journal of Hepatology**, the official journal of the European Association for the Study of the Liver.

C-SWIFT Overview and Findings

C-SWIFT (Abstract #O006) is a proof-of-concept Phase 2 open label clinical trial conducted to evaluate the efficacy and safety of grazoprevir/elbasvir plus sofosbuvir over shorter treatment durations. Specifically, treatment-naïve patients with or without liver cirrhosis chronically infected with HCV GT1 were treated for 4, 6 or 8 weeks and treatment-naïve patients with or without liver cirrhosis chronically infected with HCV GT3 were treated for 8 or 12 weeks. Interim findings were previously presented at the 65th American Association for the Study of Liver Diseases in November 2014.

Table 1 C-SWIFT Efficacy Findings – Modified Intent to Treat Analysis

Genotype	GT1		GT3				
	Treatment-Naïve Non-Cirrhotic	Treatment-Naïve Cirrhotic	Treatment-Naïve Non-Cirrhotic	Treatment-Naïve Cirrhotic			
Duration (weeks)	**4	6	6	**8	8	8	12
SVR12	33% (10/30)	87% (26/30)	80% (16/20)	94% (17/18)	93% (14/15)	100% (14/14)	91% (10/11)

**Modified intent to treat analysis excluded patients who discontinued early due to reasons other than virologic failure.

SVR12 results by treatment arm in the modified intent to treat population are shown above (table 1). Among GT1 patients, virologic relapse occurred in 20 non-cirrhotic patients receiving four weeks of treatment, in four non-cirrhotic and four cirrhotic patients receiving six weeks of treatment, and in one cirrhotic patient receiving eight weeks of treatment. Among GT3 patients, virologic relapse occurred in one non-cirrhotic patient receiving eight weeks of treatment, and in one cirrhotic patient receiving 12 weeks of treatment. There were no reported cases of virologic breakthrough.

No patients discontinued due to treatment-related adverse events. The most common adverse events reported across all treatment groups and genotypes were headache (4% overall, range 2-8% across treatment arms), fatigue (2% overall, range 0-8% across treatment arms) and nausea (2% overall, range 2-8% across treatment arms). Two serious adverse events – pyelonephritis and B-cell lymphoma – were reported but were not considered to be related to study medicine.

About Grazoprevir/Elbasvir

Grazoprevir/elbasvir is an investigational, once-daily single tablet regimen consisting of grazoprevir (NS3/4A protease inhibitor) and elbasvir (NS5A replication complex inhibitor). As part of Merck's broad clinical trials program, grazoprevir/elbasvir is being studied in multiple HCV genotypes and in patients with difficult-to-treat conditions such as HIV/HCV co-infection, advanced chronic kidney disease, inherited blood disorders, liver cirrhosis and those on opiate substitution therapy.

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 health care 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** and **YouTube**.

Forward-Looking Statement

This news release 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 Merck'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; Merck'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 Merck patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise except as required by applicable law. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck'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] Grazoprevir is a HCV NS3/4A protease inhibitor and elbasvir is a HCV NS5A replication complex inhibitor

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