



NEWS RELEASE

Merck Announces Presentation of Results from Two Phase 2 Studies of Investigational Triple-Combination Chronic Hepatitis C Therapy at The Liver Meeting®

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Merck Advances to Part B of C-CREST Phase 2 Clinical Development Program

KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced the presentation of results from the initial phase (Part A) of the company's C-CREST 1 and 2 Phase 2 clinical development program evaluating two investigational all-oral, triple-combination treatment regimens – a regimen of grazoprevir¹, MK-36822 and elbasvir³; and a regimen of grazoprevir, MK-3682 and MK-84084 – in treatment-naïve patients with chronic hepatitis C virus (HCV) genotypes (GT) 1, 2 or 3 infection. These data will be presented today during a late-breaking abstract session at **The Liver Meeting®** (Abstract #LB-15). Based on the results of this initial trial, Merck has initiated further study of grazoprevir (100mg), MK-3682 (450mg) and MK-8408 (60mg) in the second phase (Part B) of the C-CREST Phase 2 clinical development program.

“Merck’s chronic hepatitis C development program continues to focus on the goal of advancing a short-duration treatment regimen that offers high virologic cure rates across all viral genotypes,” said Dr. Roy Baynes, senior vice president and head of global clinical development, Merck Research Laboratories. “The strong results observed in this study support the further investigation of the novel triple-combination regimen of grazoprevir, MK-3682 and MK-8408 in patients with chronic hepatitis C.”

In these randomized, open-label clinical trials, **C-CREST 1** evaluated treatment-naïve, non-cirrhotic patients with chronic HCV GT1 or 2 infection and **C-CREST 2** evaluated treatment-naïve, non-cirrhotic patients with chronic HCV GT3 infection. The primary efficacy endpoint was sustained virologic response 12 weeks after the completion of



treatment (SVR12, or virologic cure). All 240 enrolled patients completed eight weeks of treatment and reached follow-up 12 weeks after end of treatment. Treatment with grazoprevir (100mg), MK-3682 (450mg) and MK-8408 (60mg), without ribavirin (RBV), for eight weeks resulted in virologic cure rates of greater than 90 percent across chronic HCV patients with GT1, 2 or 3 infection, which supported the decision to advance this regimen into Part B of the C-CREST Phase 2 clinical trial program.

Summary of SVR12 Findings Following 8 Weeks of Treatment*: C-CREST 1 and 2 Part A

Population	N	Grazoprevir + Elbasvir + MK-3682 300mg	Grazoprevir + Elbasvir + MK-3682 450mg	Grazoprevir + MK-8408 + MK-3682 300mg	Grazoprevir + MK-8408 + MK-3682 450mg
GT1	93	100% (23/23)	100% (23/23)	100% (24/24)	91% (21/23)
GT2	61	69% (11/16)	60% (9/15)	71% (10/14)	94% (15/16)
GT3	86	90% (19/21)	86% (19/22)	95% (20/21)	91% (20/22)

*Treatment-naive, non-cirrhotic patients

The most commonly reported adverse events across all regimens (greater than 10% incidence) were headache (23%), fatigue (20%) and nausea (13%). There were no drug-related serious adverse events and no discontinuations due to adverse events.

About the C-CREST Program

The C-CREST Phase 2 clinical development program is designed to evaluate the safety and efficacy of Merck's triple-combination treatment regimens in patients with chronic HCV GT1, 2 or 3 infection. The investigational medicines studied in the initial phase (Part A) of the C-CREST program included:

- Grazoprevir (MK-5172), an HCV NS3/4A protease inhibitor
- MK-3682, an oral prodrug HCV nucleotide analogue NS5B polymerase inhibitor
- Elbasvir (MK-8742), an HCV NS5A replication complex inhibitor
- MK-8408, an HCV NS5A replication complex inhibitor

Based on the results from the initial phase (Part A) in treatment-naive, non-cirrhotic chronic HCV patients, Merck has initiated further study of grazoprevir, MK-3682 and MK-8408 in the second phase (Part B) of the C-CREST Phase 2 program. Part B will evaluate the safety and efficacy of this regimen with or without RBV in chronic HCV patients with GT1, 2 or 3 infection for different treatment durations. The various study arms will include treatment-naive

patients with or without compensated cirrhosis or with HIV/HCV co-infection, as well as treatment-experienced patients (previously treated with pegylated interferon/RBV) with GT3 infection.

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 Grazoprevir is an HCV NS3/4A protease inhibitor (100mg).
2 MK-3682 is an oral prodrug HCV nucleotide analogue NS5B polymerase inhibitor (300mg or 450mg).
3 Elbasvir is an HCV NS5A replication complex inhibitor (50mg).
4 MK-8408 is an HCV NS5A replication complex inhibitor (60mg).

Merck

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