



NEWS RELEASE

Merck to Present New Data on Investigational Chronic Hepatitis C Treatment Elbasvir/Grazoprevir at The Liver Meeting® 2015, Including Phase 3 Results in Selected Difficult-to-Treat Populations

10/20/2015

New Data Will Also be Presented from Phase 2a C-CREST Trials of Merck's Investigational Triple-Combination Chronic Hepatitis C Therapies

KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced that new data from clinical trials of its investigational treatment portfolio for chronic hepatitis C virus (HCV) are scheduled to be presented at **The Liver Meeting® 2015** (the 66th annual scientific congress of the American Association for the Study of Liver Diseases) in San Francisco, from Nov. 13-17, 2015. Merck's late-stage investigational portfolio includes elbasvir/grazoprevir 1, MK-36822 and MK-84083.

A range of data will be presented from more than 20 accepted abstracts. Among these are two late-breaking abstracts from the C-CREST and C-SWIFT clinical trial programs.

"Recent innovations in the treatment of chronic hepatitis C are enabling health systems and physicians to address the burden of this disease. Continued innovation is essential, particularly for patients for whom current therapies may not be suitable," said Dr. Eliav Barr, vice president, infectious diseases, Merck Research Laboratories. "Merck is committed to evaluating our chronic hepatitis C investigational medicines in a broad range of patients and treatment durations to help address the global unmet needs that still exist."

Elbasvir/grazoprevir is currently under Priority Review with the U.S. Food and Drug Administration, with a



Prescription Drug User Fee Act (PDUFA) action date of Jan. 28, 2016.

Key Presentations of Interest

Oral Presentations for Elbasvir/Grazoprevir

Sunday, Nov. 15:

- C-EDGE CO-STAR: Efficacy of Grazoprevir and Elbasvir in Persons Who Inject Drugs (PWID) Receiving Opioid Agonist Therapy (Abstract #40, 3:45 – 4:00 p.m. PST)
- An Integrated Analysis of 402 Compensated Cirrhotic Patients With HCV Genotype (GT) 1, 4 or 6 Infection Treated With Grazoprevir/Elbasvir (Abstract #42, 4:15 – 4:30 p.m. PST)

Tuesday, Nov. 17:

- High Efficacy of Grazoprevir/Elbasvir (GZR/EBR) in HCV Genotype 1, 4, and 6-Infected Patients With HIV Coinfection: SVR24 Data From the Phase 3 C-EDGE Coinfection Study (Abstract #210, 9:15 – 9:30 a.m. PST)
- High Efficacy of Grazoprevir and Elbasvir With or Without Ribavirin in 103 Treatment-Naive and Experienced Patients With HCV Genotype 4 Infection: A Pooled Analysis (Abstract #251, 12:15 – 12:30 p.m. PST)

Late-Breaking Presentations

Monday, Nov. 16:

- Poster: Prevalence and Impact of Baseline NSA Resistance Associated Variants (RAVs) on the Efficacy of Elbasvir/Grazoprevir (EBR/GZR) against GT1a Infection (Abstract #LB-22)
- Poster: Phase 2, Randomized, Open-Label Clinical Trials of the Efficacy and Safety of Grazoprevir and MK-3682 (NS5B Polymerase Inhibitor) with Either Elbasvir or MK-8408 (NS5A Inhibitor) in Patients with Chronic HCV GT1, 2 or 3 Infection (Part A of C-CREST-1 & 2) (Abstract #LB-15)
- Poster: C-SWIFT Retreatment (Part B): 12 weeks of Elbasvir/Grazoprevir with Sofosbuvir and Ribavirin Successfully Treated GT1-infected Subjects who Failed Short-Duration All-Oral Therapy (Abstract #LB-12)

Select Poster Presentations for Elbasvir/Grazoprevir

Saturday, Nov. 14:

- Projected Long-Term Impact of Grazoprevir (GZR, MK-5172)/Elbasvir (EBR, MK-8742) in Treatment-Naive and Treatment-Experienced Patients with Hepatitis C Virus Genotype 1 Infection and Chronic Kidney Disease (Abstract #727)

- C-EDGE Co-Infection: Impact of 12-Week Oral Regimen of Grazoprevir (GZR, MK-5172)/Elbasvir (EBR, MK-8742) on Patient-Reported Outcomes (PROs) in Treatment-Naïve Patients with HCV/HIV Co-infection (Abstract #729)
- C-EDGE TN: Impact of 12-Week Oral Regimen of Grazoprevir (GZR, MK-5172)/Elbasvir (EBR, MK-8742) on Patient-Reported Outcomes (PROs) in Treatment-Naïve Patients with Chronic Hepatitis C Virus (HCV) Genotype (GT) 1, 4, or 6 Infection (Abstract #717)
- High Efficacy of the Combination HCV Regimen Grazoprevir and Elbasvir for 8 or 12 Weeks With or Without Ribavirin in Treatment-Naive, Noncirrhotic HCV GT1b-Infected Patients: An Integrated Analysis (Abstract #701)
- Predictors of Response to Grazoprevir/Elbasvir Among HCV Genotype 1 (GT1)-Infected Patients: Integrated Analysis of Phase 2-3 Trials (Abstract #700)
- Safety and Tolerability of Grazoprevir/Elbasvir in Patients With Chronic Hepatitis C (HCV) Infection: Integrated Analysis of Phase 2-3 Trials (Abstract #712)
- The Combination of Grazoprevir and Elbasvir ± RBV is Highly Effective for the Treatment of GT1a-Infected Patients (Abstract #703)
- Efficacy, Safety And Pharmacokinetics Of Grazoprevir (MK-5172) And Elbasvir (MK-8742) In Hepatitis C Genotype 1 Infected Non-Cirrhotic Japanese Patients (Phase 2 Portion In Phase 2/3 Combined Study) (Abstract #707)

For more information, including a complete list of abstract titles, please visit: <http://www.aasld.org>.

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 opiate substitution 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** and **YouTube**.

Forward-Looking Statement of Merck & Co. Inc., Kenilworth, NJ, USA

This news release of Merck & Co., Inc., Kenilworth, NJ, USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the United States 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 healthcare legislation in the United States and internationally; global trends toward healthcare 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 MK-3682 is an oral prodrug HCV nucleotide analogue NS5B polymerase inhibitor

3 MK-8408 is an HCV NS5A replication complex inhibitor

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