NEWS RELEASE

Merck Announces Results from Phase 2 Study of Investigational Chronic Hepatitis C Treatment Grazoprevir/Elbasvir in Genotype 1 Infected Treatment-Naïve and Difficult-to-Cure Patients

11/11/2014

Final Results from the C-WORTHyStudy (Parts A and B) Presented at The Liver Meeting® and Published inThe Lancet

First Wave of Phase 3 Development Program for Grazoprevir/Elbasvir is Fully Enrolled; Merck Plans to Submit New Drug Application in 2015

BOSTON--(**BUSINESS WIRE**)--Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced the presentation of results from a multi-arm Phase 2 clinical trial evaluating grazoprevir/elbasvir (MK-5172/MK-8742, the company's investigational NS3/4A protease inhibitor and NS5A inhibitor, respectively) with or without ribavirin (RBV) in treatment-naïve and previously-treated (with peg-interferon/ribavirin [PR]) patients with chronic hepatitis C virus (HCV) genotype 1 (GT1) infection -- the C-WORTHy study (Parts A and B). The final results were presented in oral sessions at the 65th American Association for the Study of Liver Diseases (AASLD) Annual Meeting (also known as The Liver Meeting®) and published as separate papers online in **The Lancet**.

"Merck is committed to developing an efficacious, well-tolerated therapy suitable for a broad spectrum of patients with HCV," said Dr. Eliav Barr, vice president, infectious diseases, Merck Research Laboratories. "We are encouraged by the findings for grazoprevir/elbasvir in the C-WORTHy trial and look forward to advancing our broad Phase 3 program, which includes hard-to-cure patients that are of the highest need and least studied to date."

Interim results from the C-WORTHy study were presented in April 2014 at the 49th Annual Meeting of the European

Association for the Study of the Liver (EASL) and announced by **Merck**.

Results for Treatment-Naïve Cirrhotic Patients and PR Null-Responders

The results for HCV mono-infected treatment-naïve GT1 patients with cirrhosis and GT1 prior null-responders with or without cirrhosis treated with grazoprevir/elbasvir, with or without ribavirin, for 12 weeks or 18 weeks are shown in table 1. The rates of sustained viral response,i 12 weeks after the completion of therapy (SVR12) were greater than, or equal to, 90 percent regardless of treatment duration or co-administration of RBV.

Table 1

Grazoprevir/ Elbasvir Treatment Duration (wks)	Treatment-Naïve Patients with Cirrhosis				PR-Nulls With or Without Cirrhosis			
	12		18		12		18	
RBV	+RBV	-RBV	+RBV	-RBV	+ RBV	- RBV	+RBV	-RBV
SVR12, n/N Percent [95% CI]	28/31 90% [74, 98]	28/29 97% [82,100]	31/32* 97% [84,100]	29/31 94% [79, 99]	30/32* 94% [79, 99]	30/33 91% [76, 98]	33/33 100% [89, 100]	31/32 97% [84, 100]
iiVirologic Failure	3†	1	0	2	0	3	0	1†

*1 treatment-naïve patient and 2 PR-null patients were lost to follow-up.

†Virologic breakthrough was seen in 1 treatment-naïve patient in the 12-wk +RBV group and in one PR-null patient in the 18-wk -RBV.

The rate of virologic failure was five percent (6/123) in treatment-naïve cirrhotic patients and three percent (4/130) in the null-responder population. Treatment was generally well-tolerated. The most common adverse events associated with the administration of grazoprevir/elbasvir in combination with or without RBV were: fatigue (26%), headache (23%) and asthenia (14%). There were no early discontinuations due to adverse events with grazoprevir/elbasvir and no clinically significant abnormalities observed in routinely evaluated biomarkers.

Results for HCV Mono-Infected and HIV/HCV Co-Infected Patients

Treatment-naïve, non-cirrhotic mono-infected GT1 patients and non-cirrhotic HCV GT1 /HIV co-infected patients treated for 12 weeks with grazoprevir/elbasvir with or without RBV, demonstrated high rates of SVR12, as seen in table 2. Among this patient population treated for 12 weeks, the overall rate of virologic failure was four percent (7/188), including three breakthrough failures and four relapses, in both mono- and co-infected patients. In patients treated for eight weeks, the rate of virologic failure was 17 percent (5/30), with five relapses. The most common adverse events with or without RBV were fatigue (23%), headache (20%), nausea (15%) and diarrhea (10%). There

were no early discontinuations due to adverse events with grazoprevir/elbasvir and no clinically significant abnormalities observed in routinely evaluated biomarkers.

Table 2

	HCV Mono-infected			HIV/HCV Co-infected	
Grazoprevir/ Elbasvir Treatment Duration (wks)	8***	12	12	12	12
RBV	+RBV	+RBV	-RBV	+RBV	-RBV
SVR12 (n/m)	80% (24/30*)	93% (79/85*)	98% (43/44)	97% (28/29)	87% (26/30*)
[95% confidence interval]	[61, 92]	[85, 97]	[88, 100]	[82, 100]	[69, 96]
iiVirologic Failure	5	3**†	1	1	2

* 4 HCV mono-infected patients (1 in the 8-wk and 3 in the 12-wk +RBV arms) and 2 HIV/HCV co-infected patients in the -RBV arm were lost to follow-up.

**Virologic breakthrough was seen in 1 patient, which was a new infection with HCV GT2b (or a minor GT2b variant at baseline).

***GT1a patients only.

†1 of the patients who relapsed did not receive grazoprevir and received only elbasvir plus RBV for the first month of treatment.

About the C-WORTHy Study

C-WORTHy is a randomized, dose response, parallel-group, multiple-site, double-blind clinical trial comparing diverse patient populations exposed to different durations of treatment of grazoprevir/elbasvir with or without RBV in patients with chronic HCV infection. In C-WORTHy Parts A and B, a total of 471 patients with chronic HCV GT1 infection with HCV RNA levels of ≥10,000 IU/mL were enrolled and randomized across 16 arms. The patients include hard-to-cure sub-populations, including treatment-naïve patients with liver cirrhosis (12- and 18-week arms, with and without RBV) and prior-null responder patients with and without cirrhosis (12- and 18-week arms, with and without RBV). The lead authors of The Lancet publications and presenters at The Liver Meeting® are Dr. Eric Lawitz of The Texas Liver Institute and professor of medicine at The University of Texas Health Science Center, San Antonio, TX (C-WORTHy Cirrhotic Patients and Prior Null-Responders); and Dr. Mark Sulkowski, professor of medicine at The Johns Hopkins University School of Medicine, Baltimore, MD (C-WORTHy HCV Mono-Infected and HIV/HCV Co-Infected Patients).

About C-EDGE: Merck's Phase 3 HCV Program

The results of the C-WORTHy study supported the advancement of grazoprevir/elbasvir into the Phase 3 clinical development program called C-EDGE. The Phase 3 C-EDGE program is evaluating grazoprevir/elbasvir with and without RBV in various genotypes and across a broad range of patient populations with chronic HCV infection, including treatment-naive patients and patients who previously failed PR therapy, patients with and without cirrhosis, patients with chronic kidney disease (including those on hemodialysis), patients with HIV/HCV co-infection, patients on opiate substitution therapy and patients with inherited blood disorders. Merck initiated the first C-EDGE study in April 2014, and the grazoprevir/elbasvir registration studies within the C-EDGE program – including C-EDGE TN (treatment-naïve), C-EDGE CO-INFXN (HIV/HCV co-infected) and C-EDGE TE (treatment-experienced) -- are now fully enrolled. Results from these trials are anticipated in the first half of 2015. Learn more at **http://www.merck.com/clinical-trials/**.

About Grazoprevir/Elbasvir

Grazoprevir/elbasvir (MK-5172/MK-8742) is an investigational, oral, once-daily, fixed-dose combination chronic HCV treatment, consisting of grazoprevir, an investigational oral, once-daily HCV NS3/4A protease inhibitor, and elbasvir, an investigational oral, once-daily HCV NS5A replication complex inhibitor. In October 2013, Merck announced that the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation to grazoprevir/elbasvir for treatment of chronic HCV 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 plans to submit the New Drug Application for grazoprevir/elbasvir in 2015.

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 healthcare 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 healthcare through far-reaching policies, programs and partnerships. For more information, visit **www.merck.com** and connect with us on **Twitter**, **Facebook** and **YouTube**.

Merck Forward-Looking Statement

This news release 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 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 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; 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’s 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. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck’s 2013 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**).

i Defined as HCV RNA below the limit of quantification or below the limit of detection at the last visit on record – 4, 8, 12, or 24 weeks after the completion of therapy.
ii Virologic failure is the inability to achieve or maintain suppression of viral replication to an HCV RNA level <200 copies/mL.

Merck
Media:
Pam Eisele, 267-305-3558
Sarra Herzog, 201-669-6570
or
Investors:

Joe Romanelli, 908-423-5185

Justin Holko, 908-423-5088