Merck Announces Results from Studies Evaluating Investigational Hepatitis C Treatments, MK-5172 and MK-8742, in Treatment-Naïve Patients with Genotype 1 Infection

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Clinical Findings Support Advancement into Phase 3 Trials

WHITEHOUSE STATION, N.J.--(BUSINESS WIRE)--Merck (NYSE:MRK), known as MSD outside of the United States and Canada, today announced additional data from the ongoing C-WORTHy study, a multi-arm Phase 2 clinical trial evaluating the efficacy and safety of a once-daily, all-oral regimen combining MK-5172, an investigational hepatitis C virus (HCV) NS3/4A protease inhibitor, and MK-8742, an investigational HCV NS5A replication complex inhibitor, among patients with chronic HCV Genotype 1 infection (GT1). In an interim analysis of treatment-naïve, non-cirrhotic patients administered a 12-week regimen of MK-5172/MK-8742, with and without ribavirin (RBV), a sustained viral response¹ (SVR) was observed in 98 percent (42/43) of patients administered MK-5172/MK-8742 alone and 94 percent (75/80) in those administered MK-5172/MK-8742 plus RBV. These data were presented, along with data on an 8-week regimen, at the 49th Annual Meeting of the European Association for the Study of the Liver (EASL), also known as The International Liver Congress™ 2014, in London, UK.

“These Phase 2 results add to growing evidence for the potential efficacy of MK-5172 and MK-8742 for treatment of chronic HCV infection,” said Dr. Eliav Barr, vice president, Infectious Diseases, Merck Research Laboratories. “These findings are integral to advancing our research of these investigational candidates into C-EDGE, the Phase 3 clinical program that will seek to more broadly evaluate the potential of MK-5172/MK-8742 in diverse patient populations.”

C-WORTHy Study Design

C-WORTHy is a two-part, parallel-group, randomized (within group) clinical trial evaluating a range of subpopulations of patients with HCV GT1 infection. The study evaluated different treatment durations of MK-5172 (100 mg once daily) plus MK-8742 (50 mg once daily), with or without RBV. A total of 471 patients with HCV GT1 RNA levels of ≥10,000 IU/mL were enrolled in C-WORTHy across 16 arms.

Key Findings for MK-5172/MK-8742

The interim results presented were from treatment-naïve, non-cirrhotic patients who received one of 3 regimens: A) MK-5172/MK-8742 + RBV for 8 weeks (N=30), B) MK-5172/MK-8742 + RBV for 12 weeks (N=85), and C) MK-5172/MK-8742 (without RBV) for 12 weeks (N=44), (see table 1).

Table 1 - Interim Results from the C-WORTHy Trial Showing Treatment-Naive, Non-Cirrhotic Patients with HCV GT1 Infection (Intention-to-Treat (ITT) Analysis)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>MK-5172 + MK-8742 (NO RBV) (12 Weeks) (N = 44)</th>
<th>MK-5172 + MK-8742 + RBV (12 Weeks) (N = 85)</th>
<th>MK-5172 + MK-8742 + RBV (8 Weeks) (N = 30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SVR4-24†, % (n)</td>
<td>98% (43)</td>
<td>94% (80)</td>
<td>83% (25)</td>
</tr>
<tr>
<td>No SVR, % (n)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breakthrough</td>
<td>0</td>
<td>1% (1)</td>
<td>0</td>
</tr>
<tr>
<td>Relapse</td>
<td>2% (1)</td>
<td>1% (1)</td>
<td>17% (5)</td>
</tr>
</tbody>
</table>
### PN038 Study Design and Findings

Additionally, new data from PN038, a Phase 2 dose-ranging clinical trial evaluating MK-5172 once-daily with peginterferon alfa-2b and ribavirin (PR, weekly), were presented, evaluating SVR24 in treatment-naïve, non-cirrhotic patients with GT1 infection. PN038 is a Phase 2 clinical trial investigating the efficacy and safety of MK-5172 doses (25 mg, 50 mg, and 100 mg) once-daily with PR over a 12-week treatment cycle in GT1 treatment-naïve, non-cirrhotic patients (n=87). The analysis presented was ITT, in which all patients who did not achieve SVR (including those who dropped out for non-virologic reasons), were recorded as failures.

MK-5172 at doses of 50 mg and 100 mg with PR for 12 weeks of treatment achieved SVR24 rates of 75.0 percent (21/28) and 83.3 percent (25/30), respectively, supporting use of MK-5172 below 100 mg dose (see table 2).

### Table 2: PN038 Virologic Responses - (ITT Analysis)

<table>
<thead>
<tr>
<th>Patients with HCV RNA &lt;25 IU/mL / total # of patients (%)</th>
<th>MK-5172 25 mg with PR (N=29)</th>
<th>MK-5172 50 mg with PR (N=28)</th>
<th>MK-5172 100 mg with PR (N=30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TW*4</td>
<td>93.1% (27/29)</td>
<td>96.4% (27/28)</td>
<td>100.0% (30/30)</td>
</tr>
<tr>
<td>TW12</td>
<td>93.1% (27/29)</td>
<td>96.4% (27/28)</td>
<td>96.7% (29/30)</td>
</tr>
<tr>
<td>SVR12</td>
<td>48.3% (14/29)</td>
<td>75.0% (21/28)</td>
<td>86.7% (26/30)</td>
</tr>
<tr>
<td>SVR24</td>
<td>48.3% (14/29)</td>
<td>75.0% (21/28)</td>
<td>83.3% (25/30)</td>
</tr>
</tbody>
</table>

*Treatment week

The most common recorded adverse experiences recorded across all treatment arms were: fatigue (61%), headache (46%), nausea (43%), and decreased appetite (43%). These adverse experiences did not appear to be dose-related.

One patient discontinued therapy after seven days of dosing with MK-5172 100 mg, plus PR and experienced muscle inflammation (creatinine kinase >5x upper limits of normal [ULN]), elevated transaminases to >3x ULN, and total bilirubin >2x ULN, associated with a positive toxicology screen for ethanol. There were no other clinically significant transaminase elevations recorded in this study.

### About Merck’s Phase 3 HCV Program: C-EDGE

Based on the results of the Phase 2 clinical program, Merck has initiated Phase 3 clinical trials for MK-5172/MK-8742. The Phase 3 program, called C-EDGE, will evaluate the safety and efficacy of MK-5172/MK-8742 with and without ribavirin in various genotypes and across a broad range of patient populations with chronic HCV. Study cohorts will include: C-EDGE TN (GT1, GT4-6; treatment-naïve ± cirrhosis), C-EDGE CO-INF (GT1, GT4-6; treatment-naïve ± cirrhosis with HIV/HCV co-infection), C-EDGE RECOVERY (GT1, GT4-6; treatment-naïve ± cirrhosis; ± HIV/HCV co-infection on opiate substitution therapy), and C-EDGE TE (GT1, GT4-6; prior failed treatment with peginterferon/ribavirin; ± HIV/HCV co-infection). Study information can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### About Merck’s Commitment to HCV

For more than 25 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 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 of the United
States and Canada. Through our prescription medicines, vaccines, biologic therapies, and consumer care 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 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’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).

1 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.

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Exchange: NYSE