

Phase 3 UNITY Trials Demonstrate High Cure Rates for Investigational, All-Oral Daclatasvir TRIO Fixed-Dose Combination in Genotype 1 Hepatitis C Patients, Including Those with Cirrhosis

Daclatasvir TRIO achieves 98% cure rate in treatment-naïve and 93% cure rate in treatment-experienced genotype 1 patients with cirrhosis when used with ribavirin, as shown in UNITY 2

12-week, all-oral treatment halves current regimen duration for hard-to-manage treatment-experienced genotype 1 patients with cirrhosis

Fixed-dose regimen also demonstrates 91% SVR rates in non-cirrhotic genotype 1 patients without requiring use of ribavirin

Saturday, November 8, 2014 9:00 am EST-- "BMS continues to recognize that HCV is an extremely complicated disease with no 'one-size-fits-all' treatment solution, and the UNITY results are especially promising for serving patients with cirrhosis, a specific but significant portion of genotype 1 patients."

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMJ) today announced late-breaking data from the UNITY Trial program investigating a 12-week regimen of its all-oral daclatasvir (DCV) TRIO regimen – a fixed-dose combination of daclatasvir with asunaprevir (ASV) and beclabuvir (BCV) – in a broad range of patients with genotype 1 hepatitis C virus (HCV). The data will be presented at The Liver Meeting® 2014, the Annual Meeting of The American Association for the Study of Liver Diseases (AASLD), in Boston, MA, November 7 – 11. The primary endpoint for both studies was the percentage of patients who achieved cure, defined as HCV RNA < LLOQ TD/TND at post-treatment week 12 for treatment-naïve and treatment-experienced patients.

The UNITY-2 study, which evaluated cirrhotic patients in a 12-week regimen of the DCV-TRIO, showed sustained virologic response 12 weeks after treatment (SVR12) among 98% of treatment-naïve and 93% of treatment-experienced cirrhotic patients with ribavirin (RBV) and 93% of treatment-naïve and 87% of treatment-experienced cirrhotic patients without ribavirin.

"Even with the most recent HCV treatment advances, genotype 1 patients with cirrhosis remain difficult to treat," said Andrew J. Muir, M.D., MHS, Associate Professor of Medicine; Clinical Director, Gastroenterology & Transplant Hepatology, Duke Gastroenterology. "Currently, treatment-experienced cirrhotic patients still require a 24-week regimen to achieve high SVR rates. The data from this clinical trial using the DCV-TRIO regimen showed high cure rates for this population in a 12-week regimen, and has the potential to aid treatment adherence and provide a shorter treatment duration to achieve cure."

Study Design and Results

The Phase 3 UNITY clinical trial program is an ongoing study investigating 12-week regimens of the DCV-TRIO fixed-dose combination (daclatasvir 30 mg plus asunaprevir 200 mg plus beclabuvir 75 mg) in non-cirrhotic and cirrhotic genotype 1 patients.

The open-label UNITY-1 study evaluated a 12-week regimen of the DCV-TRIO without ribavirin in treatment-naïve and -experienced non-cirrhotic patients. Non-cirrhotic treatment-naïve patients (n=312) and treatment-experienced patients (n=103) received the DCV-TRIO fixed-dose combination in one pill twice daily for 12 weeks, with 24 weeks of follow-up. The majority of the patients (73%) were genotype 1a, and 91% of all patients achieved SVR12. 92% of treatment-naïve patients and 89% of treatment-experienced patients achieved cure, without the use of ribavirin.

In the UNITY-2 study, both cirrhotic treatment-naïve and treatment-experienced patients received the DCV-TRIO fixed-dose combination, one arm without ribavirin (n=102) and one with ribavirin (n=100). The study was double-blinded to ribavirin, and the majority of the patients (74%) were genotype 1a. The study showed 96% of all patients who received the DCV-TRIO with ribavirin achieved SVR12, and 90% of those who received the DCV-TRIO without ribavirin achieved SVR12.

“The Phase 3 UNITY results for the daclatasvir TRIO fixed-dose combination are particularly compelling for genotype 1 patients with cirrhosis, whose treatment is often harder to manage than non-cirrhotic patients,” said Douglas Manion, M.D., head of Specialty Development, Bristol-Myers Squibb. “BMS continues to recognize that HCV is an extremely complicated disease with no ‘one-size-fits-all’ treatment solution, and the UNITY results are especially promising for serving patients with cirrhosis, a specific but significant portion of genotype 1 patients.”

In both UNITY-1 and UNITY-2 there were low rates of adverse events (AEs) leading to discontinuation and of serious adverse events (SAEs) overall. In UNITY-1 there were 7 SAEs, all considered not related to study treatment, and 3 AEs leading to treatment discontinuation. The most common AEs were headache (25.8%) and fatigue (16.6%). In UNITY-2, there were 3 SAEs related to treatment and 4 AEs leading to discontinuation. The most common AEs were headache and fatigue (both 19.8%).

Full abstracts for both presentations are available at [The Liver Meeting website](#).