ALLY Trial Demonstrates High Cure Rates for Investigational Daclatasvir and Sofosbuvir Combination among Genotype 3 Hepatitis C Patients

Daclatasvir+sofosbuvir regimen achieves SVR12 in 90% of treatment-naïve and 86% of treatment-experienced genotype 3 patients
ALLY-3 is the first Phase 3 study of an all-oral, ribavirin-free treatment regimen for genotype 3 HCV patients with a 12-week treatment duration
Genotype 3 is the second most common genotype worldwide and has emerged as one of the most difficult to treat

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PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) today announced late-breaking data from the landmark ALLY Trial investigating a ribavirin-free 12-week regimen of daclatasvir (DCV) in combination with sofosbuvir (SOF) in genotype 3 hepatitis C (HCV) patients, a patient population that has emerged as one of the most difficult to treat. The results of the study, which showed sustained virologic response 12 weeks after treatment (SVR12) in 90% of treatment-naïve and 86% of treatment-experienced patients, 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.

“Both treatment naïve and treatment experienced patients in the ALLY-3 study achieved high SVR rates. These results are encouraging given that patients with genotype 3 have emerged as among the hardest to treat,” said David R. Nelson, M.D., Professor of Medicine, Molecular Genetics and Microbiology Director, UF Clinical and Translational Science Institute, and Assistant Vice President of Research for the University of Florida. “Genotype 3 is associated with a more rapid progression of disease and remains a challenge to the efficacy of even newer regimens. The ALLY-3 results demonstrate the possibility of bringing a cure to genotype 3 patients in an all-oral, 12-week regimen.”

These results build upon the existing body of data on the daclatasvir and sofosbuvir combination. Data from an open-label, randomized study of daclatasvir with sofosbuvir in genotypes 1, 2, and 3 demonstrated that the 24-week regimen of daclatasvir and sofosbuvir (± ribavirin) achieved SVR12 in 89% of patients with genotype 3. The ALLY study presented at The Liver Meeting investigates the regimen for 12 weeks, halving the previous treatment duration. Other ongoing ALLY studies examine diverse HCV populations across all genotypes: cirrhotic and post-liver transplant patients, as well as treatment-naïve and treatment-experienced patients who are co-infected with HIV.

“HCV is a complex disease, and the treatment community needs multiple options to address the remaining unmet medical needs,” said Douglas Manion, M.D., head of Specialty Development, Bristol-Myers Squibb. “Daclatasvir has shown pan-genotypic activity in bench research, a factor which is becoming increasingly important as we learn more about the complexity of HCV. Further, daclatasvir’s

potential to be combined with many other agents, including sofosbuvir, is significant in continuing to develop additional treatment options that may help patients of all genotypes achieve cure."
In the ALLY-3 study, the daclatasvir and sofosbuvir combination regimen was well tolerated, with no deaths, treatment-related serious adverse events, or discontinuations due to adverse events. The most frequent side effects (≥5%) were headache (19.7%), fatigue (19.1%), nausea (11.8%), diarrhea (8.6%), insomnia (5.9%), abdominal pain and arthralgia (both 5.3%). Additionally, there were 17 (11.2%) treatment failures, with 16 relapses post-treatment and 1 rebound at the end of treatment. There were no viral breakthroughs in this ribavirin-free regimen.

About ALLY-3: Study Design
This Phase 3 open-label clinical trial enrolled 152 genotype 3 HCV patients; 101 treatment-naïve patients and 51 treatment-experienced patients in 2 cohorts each received daclatasvir 60 mg and sofosbuvir 400 mg once daily for 12 weeks, with 24 weeks of follow-up. The primary endpoint was SVR12 rates, defined as HCV RNA < LLOQ target detected or not detected at follow-up week 12 in treatment-naïve and treatment-experienced patients.
- See more at: http://hepatitisresearchandnewsupdates.blogspot.com/2014/11/ally-trial-demonstrates-high-cure-rates.html#sthash.CFVt0Lb4.dpuf