Bristol-Myers Squibb Receives U.S. FDA Breakthrough Therapy Designation for All-Oral Daclatasvir Dual Investigational Regimen for Chronic Hepatitis C

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- FDA grants Designation request for investigational daclatasvir (DCV) and asunaprevir (ASV) combination therapy for treatment of genotype 1b chronic hepatitis C (HCV) infection
- Marks second Breakthrough Therapy Designation for a daclatasvir-based regimen; 3DAA regimen granted Designation in 2013

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) today announced that the U.S. Food and Drug Administration (FDA) has granted its investigational DCV Dual Regimen (daclatasvir and asunaprevir) Breakthrough Therapy Designation for use as a combination therapy in the treatment of genotype 1b chronic hepatitis C infection (HCV). The designation is based on data from the company’s ongoing Phase III clinical trial program evaluating the all-oral combination regimen of DCV, an investigational NS5A replication complex inhibitor, and ASV, an investigational NS3 protease inhibitor, without ribavirin.

According to the FDA, Breakthrough Therapy Designation is intended to expedite the development and review of drugs for serious or life-threatening conditions. The criteria for Breakthrough Therapy Designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy.

“The FDA’s decision to grant Breakthrough Therapy Designation for our DCV Dual Regimen (daclatasvir and asunaprevir combination therapy) marks the second time that the FDA has granted the Designation to a daclatasvir-based regimen, further underscoring its potential to help address the high unmet needs of the HCV patient population,” said Brian Daniels, MD, senior vice president, Global Development and Medical Affairs, Research and Development, Bristol-Myers Squibb. “This is an important milestone for Bristol-Myers Squibb as we continue our strategic focus on the development of innovative medicines to address areas of high unmet medical need, where potential expedited review can make a critical difference for patients.”

Approximately 170 million people worldwide are infected with hepatitis C, with an estimated 2.7-3.9 million chronically infected in the U.S. Many of these people have been living with HCV for decades, putting them at heightened risk for developing serious, potentially life-threatening liver disease.

New data from Bristol-Myers Squibb’s ongoing Phase III clinical program studying the DCV Dual Regimen is anticipated to be presented at an upcoming scientific forum. Data from a separate daclatasvir and asunaprevir Phase III trial in Japanese patients with HCV genotype 1b who were either interferon-ineligible/intolerant or non-responders (null and partial) to interferon-based therapies served as the basis for a regulatory filing in Japan in October 2013.

Bristol-Myers Squibb also recently announced that the European Medicines Agency (EMA) validated the company’s marketing authorization application (MAA) for the use of daclatasvir for the treatment of adults with HCV with compensated liver disease, including genotypes 1, 2, 3, and 4. The application seeks the approval of daclatasvir for use in combination with other agents for the treatment of chronic hepatitis C and will be reviewed under an accelerated regulatory review.

About Hepatitis C

Hepatitis C is a virus that infects the liver and is transmitted through direct contact with infected blood and blood products. Up to 90 percent of those infected with hepatitis C will not spontaneously clear the virus and will become chronically infected. According to the World Health Organization, 20 percent of people with chronic hepatitis C will develop cirrhosis and, of those, up to 25 percent may progress to liver cancer.

About Bristol-Myers Squibb’s HCV Portfolio

Bristol-Myers Squibb’s research efforts are focused on advancing late-stage compounds to deliver the most value to patients with hepatitis C. At the core of our pipeline is daclatasvir, an investigational NS5A replication complex inhibitor that has been studied in more than 5,500 patients as a foundational agent for multiple direct-acting antiviral (DAA) based combination therapies.
In 2013, Bristol-Myers Squibb's investigational all-oral 3DAA Regimen (daclatasvir/asunaprevir/BMS-791325) received FDA Breakthrough Therapy Designation, which helped to expedite the start of the ongoing Phase III UNITY Program. Study populations include non-cirrhotic treatment naive and experienced patients, as well as cirrhotic treatment naive and experienced patients. The daclatasvir 3DAA regimen is being studied as a fixed-dose-combination treatment with twice daily dosing.

In addition, enrollment has begun for the Phase III ALLY Program, in which daclatasvir in combination with sofosbuvir, is being studied in high unmet need patients, such as pre- and post-transplant patients, HIV/HCV co-infected patients and patients infected with HCV genotype 3.

Other compounds in the pipeline include:

- Asunaprevir (ASV) is an investigational NS3 protease inhibitor for hepatitis C which has been studied as a component of DCV-based treatment regimens
- BMS-791325 is a non-nucleoside inhibitor of the NS5B polymerase, currently in Phase III development for hepatitis C as a component of DCV-based treatment regimens
- Peginterferon lambda is an investigational type III interferon that has the potential to offer an alternative to peginterferon alfa in patients for whom an interferon-based regimen is required or preferred

**About Bristol-Myers Squibb**

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information, please visit [http://www.bms.com](http://www.bms.com) or follow us on Twitter at [http://twitter.com/bmsnews](http://twitter.com/bmsnews).

**Bristol-Myers Squibb Forward Looking Statement**

This press release contains “forward-looking statements” as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding the research, development and commercialization of pharmaceutical products. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. Among other risks, there can be no guarantee that DCV or any other compounds mentioned in this release will receive regulatory approval or, if approved, that they will become commercially successful products. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Bristol-Myers Squibb's business, particularly those identified in the cautionary factors discussion in Bristol-Myers Squibb's Annual Report on Form 10-K for the year ended December 31, 2013, in our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K. Bristol-Myers Squibb undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

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