Bristol-Myers Squibb Submits NDAs for Daclatasvir and Asunaprevir to US FDA for the Treatment of Hepatitis C

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U.S. application submission marks third major daclatasvir regulatory milestone globally, follows E.U. and Japan

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) announced today that they have submitted new drug applications (NDAs) with the U.S. Food and Drug Administration (FDA) for the investigational products daclatasvir (DCV), an NS5A replication complex inhibitor, and asunaprevir (ASV), a NS3 protease inhibitor. The data submitted in the NDAs support the use of DCV+ASV in patients with genotype 1b hepatitis C (HCV). The DCV NDA also seeks approval for use of this compound in combination with other agents for multiple genotypes. The submissions are subject to FDA review for acceptance for filing.

“These FDA submissions represent a major step towards offering daclatasvir-based regimens to U.S. HCV patients, many of whom continue to have high unmet medical needs,” said Brian Daniels, MD, senior vice president, Global Development and Medical Affairs, Research and Development, Bristol-Myers Squibb. “We are excited to have achieved this milestone and, looking forward, will continue to innovate and invest in daclatasvir in a range of patient types and regimens.”

These submissions follow the recent announcement that the FDA granted the investigational DCV Dual Regimen (DCV+ASV) Breakthrough Therapy Designation. In 2013, the investigational all-oral 3DAA Regimen (daclatasvir/asunaprevir/BMS-791325) also received Breakthrough Therapy Designation, and the company anticipates submitting this regimen for FDA review in Q1 2015.

In January 2014, the European Medicines Agency (EMA) validated the company’s marketing authorization application for the use of DCV in combination with other agents for the treatment of adults with HCV with compensated liver disease, including genotypes 1, 2, 3, and 4, and this application is under accelerated review. In addition, NDAs for DCV and ASV are under priority review by Japan's Pharmaceutical and Medical Devices Agency for patients with chronic HCV genotype 1b, classified as either interferon-ineligible naïve/intolerant or non-responders to interferon and ribavirin.

About Hepatitis C

Hepatitis C is a virus that infects the liver and is transmitted through direct contact with infected blood and blood products. Approximately 170 million people worldwide are infected with hepatitis C, with an estimated 2.7–3.9 million chronically infected in the United States. 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, up to 20 percent of people with chronic hepatitis C will develop cirrhosis; 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 (DCV), an investigational NS5A replication complex inhibitor that has been studied in more than 5,500 patients as part of multiple direct-acting antiviral (DAA) based combination therapies. DCV has shown a low drug-drug interaction profile, supporting its potential use in multiple treatment regimens and in people with co-morbidities.

DCV is currently being studied in the ongoing Phase III UNITY Program, where it is being investigated as part of an all-oral 3DAA Regimen (daclatasvir/asunaprevir/BMS-791325). Study populations include non-cirrhotic naïve, cirrhotic naïve and previously treated patients. The 3DAA Regimen is being studied as a fixed-dose-combination treatment with twice daily dosing.

Daclatasvir is also being investigated in combination with sofosbuvir in high unmet need patients, such as pre- and post-transplant patients, HIV/HCV co-infected patients, and patients with genotype 3, as part of the ongoing Phase III ALLY Program.

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 or follow us on Twitter at 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 clinical trials of these compounds will support regulatory filings, or 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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