Japan Approves First All-Oral, Interferon- and Ribavirin-Free Hepatitis C Treatment, Daklinza® (daclatasvir) and Sunvepra® (asunaprevir) Dual Regimen

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Offers new treatment option for genotype 1 HCV patients in Japan who are interferon-ineligible/intolerant, or did not previously respond to treatment

Japanese HCV patients in urgent need of care now have opportunity for cure, including older patients and those with compensated cirrhosis

Of the 1.2 million people living with HCV in Japan, approximately 70% have genotype 1b. Further, a significant number of patients with HCV in Japan are over the age of 65, leading to more disease-related complications and a decreased likelihood of tolerating interferon-based therapies, the historical standard of care for treating HCV.

“The approval of Daklinza+Sunvepra in Japan reflects our strategic focus on developing a treatment option that meets the needs of the Japanese HCV patient population,” said Lamberto Andreotti, chief executive officer, Bristol-Myers Squibb. “This milestone underscores the company’s commitment to delivering innovative medicines to patients with the highest unmet needs, and we believe Daklinza-based regimens will play a significant role in the evolution of HCV treatment for patients in Japan, and globally.”
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, a potent pan-genotypic NS5A complex inhibitor (in vitro), which continues to be investigated in multiple treatment regimens and in people with co-morbidities, and is undergoing regulatory review in the U.S. and Europe.

Daclatasvir is being studied 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.

In 2014, the U.S. Food and Drug Administration (FDA) granted Bristol-Myers Squibb’s investigational Daclatasvir+Asunaprevir Dual Regimen Breakthrough Therapy Designation for use as a combination therapy in the treatment of genotype 1b HCV infection.

In 2013, Bristol-Myers Squibb’s investigational all-oral 3DAA Regimen (daclatasvir/asunaprevir/BMS-791325) also received Breakthrough Therapy Designation in the U.S., which helped to expedite the start of the ongoing Phase III UNITY Program. Study populations include non-cirrhotic naïve, cirrhotic naïve and previously treated patients. The daclatasvir 3DAA regimen is being studied as a fixed-dose-combination treatment with twice daily dosing.

About Hepatitis C

Globally, there are 150 million people infected with HCV, with genotype 1 being the most prevalent. 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, about 5 to 7 percent of patients may ultimately die of the consequences of infection.

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.

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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 daclatasvir or asunaprevir or any other compounds mentioned in this release will receive regulatory approval in other countries or 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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