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

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) announced today that the Japanese Ministry of Health, Labor and Welfare (MHLW) has approved Daklinza® (daclatasvir), a potent, pan-genotypic NS5A replication complex inhibitor (in vitro), and Sunvepra® (asunaprevir), a NS3/4A protease inhibitor, providing a new treatment that can lead to cure for many patients in Japan who currently have no treatment options. The Daklinza+Sunvepra Dual Regimen is Japan's first all-oral, interferon- and ribavirin-free treatment regimen for patients with genotype 1 chronic hepatitis C virus (HCV) infection, including those with compensated cirrhosis.

“Japan has a unique hepatitis C patient population, many of whom are older and have been unable to take, or respond to, traditional therapies, so we have a real sense of urgency to treat these patients now,” said a lead study investigator Kazuaki Chayama of Hiroshima University in Japan. “The approval of the Daklinza+Sunvepra Dual Regimen offers for the first time a treatment option that addresses many of the unmet needs for our HCV patients.”

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.”

The Daklinza+Sunvepra Dual Regimen

The indications for Daklinza and Sunvepra in Japan are for the improvement of viraemia in either of the following patients with chronic hepatitis C genotype 1, or chronic hepatitis C genotype 1 with compensated cirrhosis: (1) patients who are ineligible or intolerant to interferon-based therapy, and (2) patients who have failed to respond to interferon-based therapy.

The approval is supported by results from a Phase III study demonstrating that the 24-week regimen of Daklinza and Sunvepra achieved overall SVR24 (sustained virologic response 24 weeks after the end of treatment; a functional cure) among 84.7% of Japanese HCV patients with genotype 1b. Among patients 65 years of age or older who were either interferon-ineligible or intolerant, 91.9% achieved SVR24. Further, patients with compensated cirrhosis present at baseline had overall SVR24 rates of 90.9%.

The regimen used in the Phase III study resulted in low rates of discontinuation (5%) due to adverse events (AEs). In addition, the rate of serious adverse events (SAEs) was low (5.9%) and few SAEs were experienced by more than one patient. Nasopharyngitis was the most common AE in the study (30.2%).

Results from the HALLMARK-Dual study, the Phase III multinational clinical trial investigating the Daklinza+Sunvepra Dual Regimen among genotype 1b HCV patients, demonstrated similar results to the Japan registration study and support filings in countries that have a high prevalence of genotype 1b, such as Korea and Taiwan.

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, 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.

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 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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