Bristol-Myers Squibb

**Daclatasvir Marketing Authorization Application for Treatment of Chronic Hepatitis C Validated for Accelerated Regulatory Review by the European Medicines Agency**

- *Bristol-Myers Squibb application supports use of daclatasvir in combination with other agents for treating HCV patients with genotypes 1, 2, 3 and 4*
- *Submission includes EU's first all-oral and ribavirin-free investigational regimen − for use in treatment naïve genotype 1, 2, 3 patients and protease inhibitor treatment failures*
- *Company is prepared to work with authorities across Europe to help ensure daclatasvir is reimbursed for HCV patients with high unmet needs, if daclatasvir is approved*

(PRINCETON, N.J., January 8, 2014) – Bristol-Myers Squibb Company (NYSE: BMY) today announced that the European Medicines Agency (EMA) has validated the company's marketing authorization application (MAA) for the use of daclatasvir (DCV), an investigational NS5A complex inhibitor, for the treatment of adults with chronic hepatitis C (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, including sofosbuvir, for the treatment of chronic hepatitis C. The MAA validation marks the start of an accelerated regulatory review process for DCV, which has the potential, when used in combination with other agents, to address a high unmet need in the European Union (EU) where an estimated 9 million people are living with hepatitis C.[i]

"Our extensive clinical trial program has demonstrated that daclatasvir has potential use as a foundational agent for multiple HCV treatment regimens," said Brian Daniels, MD, senior vice president, Global Development and Medical Affairs, Research and Development, Bristol-Myers Squibb. "If daclatasvir is approved, we would focus on helping to ensure its availability to patients with limited treatment options and would work with EU health authorities to ensure access is achieved as quickly as possible."

In the European Union, the burden of liver disease and other morbidities from HCV infection is significant, with large numbers of patients in urgent need of new treatment options.[ii] Because of the progressive nature of HCV, decades may pass before patients become symptomatic. Many of these aging patients develop liver disease, making them more difficult to treat with the current standard of care of interferon plus ribavirin with or without a protease inhibitor.[iii] Viral hepatitis has also been cited as a cause for the increase in the incidence of HCC (hepatocellular carcinoma) in Europe.[iv]

The EMA submission is supported by data from multiple studies of daclatasvir with other HCV therapies. To date, DCV has been studied in more than 5,500 patients in a variety of all-oral regimens and with the current interferon-based standard of care. In addition to demonstrating pan-genotypic potency *in vitro*, DCV has shown a low drug-drug interaction profile, supporting its potential use in multiple treatment regimens and in people with co-morbidities. No clinically relevant safety signals have been observed thus far in DCV clinical trials, and DCV has been generally well-tolerated in all investigational regimens and patient types.

The EU submission follows the recent Bristol-Myers Squibb regulatory filing in Japan seeking approval of a DCV-based regimen for the treatment of patients infected with HCV genotype 1b.

**About Hepatitis C**

Hepatitis C is a virus that infects the liver and is transmitted through direct contact with infected blood and blood products.[v] An estimated 170 million people worldwide are infected with hepatitis C.[vi] Up to 90 percent of those infected with hepatitis C will not clear the virus and will become chronically infected.[vii]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.[viii,ix,]

**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 extensively studied as a foundational agent for multiple direct-acting antiviral (DAA) based combination therapies.

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 with other Bristol-Myers Squibb investigational agents. Study populations include non-cirrhotic naïve, cirrhotic naïve and previously treated patients. Additional Phase III clinical trials are planned to start in early 2014.

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 alfa-interferon 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 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 DCV will receive regulatory approval or, if approved, that it will become a commercially successful product. 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, 2012, 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.*

# # #

Contact:

**Media:**

Carrie Fernandez,
Office: 609-252-4831; Cell: 215-859-2605
carrie.fernandez@bms.com

Jeff Smith
Office: +33(0)1 58 83 83 21; Cell: +33(0) 6 03 99 40 18
JR.Smith@bms.com

**Investors:**

Ranya Dajani, 609-252-5330, ranya.dajani@bms.com
Ryan Asay, 609-252-5020, ryan.asay@bms.com

---

[i] Vietri J, Prajapati G, El Khoury AC. "The burden of hepatitis C in Europe from the patients' perspective" BMS Gastroenterol. 2013 Jan 17; 13:16

[ii] European Centre for Disease prevention and Control. Hepatitis B and C in the EU neighbourhood: prevalence, burden of disease and screening policies. 2010; 1-56. P17. Table 2

[iii] Poordad F, Dieterich D, Treating hepatitis C: current standard of care and emerging direct-acting antiviral agents, Journal of Viral Hepatitis, Volume 19, Issue 7, pages 449–464, July 2012; http://refhub.elsevier.com/S0168-8278(13)00209-2/h0015

[iv] Venook

[v] Centers for Disease Control and Prevention. "Hepatitis C Information for the Public," http://www.cdc.gov/hepatitis/c/. Accessed Dec. 21, 2013

[vi] Averhoff FM, et al. Clin Infect Dis 2012;55(S1):S10-S15

[vii] World Health Organizations (WHO). "Hepatitis C: About HCV Infection." Accessed at: http://www.who.int/csr/disease/hepatitis/whocdscsrylo2003/en/index3.html.

[viii] World Health Organization (WHO). "Hepatitis C." Accessed at: http://www.who.int/csr/disease/hepatitis/Hepc.pdf. Page 4.

[ix] EASL International Consensus Conference on Hepatitis C. Consensus Statement. Journal of Hepatology, 1999, 31:3-8.