Bristol-Myers Squibb to Present Data for Daclatasvir in Multiple Investigational All-oral Combinations across Hepatitis C Genotypes at The International Liver CongressTM

**Release Date:**
Monday, March 24, 2014 5:39 am EDT

**Terms:**
R&D News

**Dateline City:**
PRINCETON, N.J.

Daclatasvir data demonstrates potential to address high unmet needs, including cirrhotic and treatment-experienced patients, and those with genotypes 1, 2, 3 and 4

Breadth of viral hepatitis data underscores Company’s commitment to advancing research of liver diseases

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) announced today that 12 abstracts have been accepted for presentation at The International Liver CongressTM, the 49th annual meeting of the European Association for the Study of the Liver (EASL), in London, April 9 – 13.

Key presentations include:

- Two sets of pivotal results from a global, Phase III study (HALLMARK DUAL) investigating the efficacy and safety of an all-oral, interferon- and ribavirin-free regimen of daclatasvir and asunaprevir, including data in cirrhotic and non-cirrhotic patients with HCV genotype 1b infection, will be presented as late-breakers.
- Virologic response results from analyses investigating daclatasvir in combination with sofosbuvir across genotypes 1, 2 and 3.
- Virologic response and safety data for the investigational all-oral 3DAA regimen (daclatasvir/asunaprevir/BMS-791325) in genotype 4 patients, as well as bioequivalence data for the daclatasvir 3DAA regimen, which is being studied as a fixed-dose-combination treatment with twice daily dosing.

“These results are encouraging and show the potential of daclatasvir across multiple treatment regimens, with the goal of helping patients achieve cure regardless of genotype, stage of disease or response to previous therapies,” said Brian Daniels, MD, senior vice president, Global Development and Medical Affairs, Research and Development, Bristol-Myers Squibb.

“The wealth of data we are sharing at the International Liver Congress continue the positive momentum for daclatasvir after the Marketing Authorization Application was validated for Accelerated Regulatory Review by the European Medicines Agency, highlighting the important potential role for daclatasvir-based regimens in Europe.”

Bristol-Myers Squibb is studying a broad portfolio of compounds in hopes of providing flexible treatment options to address the diverse unmet medical needs of a global HCV patient population. These investigational compounds include daclatasvir, an investigational NS5A replication complex inhibitor that has shown high antiviral potency and pan-genotypic activity across HCV genotypes in vitro; asunaprevir, an investigational NS3 protease inhibitor; BMS-791325, an investigational non-nucleoside inhibitor of the NS5B polymerase; and peginterferon lambda-1a (Lambda), an investigational type III interferon that has the potential to offer an alternative to alfa-interferon.


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<thead>
<tr>
<th>Title</th>
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<td><strong>Hepatitis C: Direct-Acting Antiviral Data</strong></td>
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<td>Oral Presentation (late-breaker): All-oral dual therapy with daclatasvir and asunaprevir in patients with HCV genotype 1b infection: Phase 3 study results</td>
<td>April 12, 15:30 - 17:30</td>
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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 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.

**Language:**
English

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*Ticker:* BMY  
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