Bristol-Myers Squibb to Present New Data on Hepatitis C and Hepatitis B Compounds at The International Liver Congress™ (ILC) 2013

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- New data on an investigational, all-oral, triple DAA regimen of daclatasvir, asunaprevir and BMS-791325 to be included in official ILC Press Conference on April 24
- New ALT flare data further characterize profile of peginterferon lambda-1a (Lambda) as investigational treatment for Chronic Hepatitis B (CHB)
- Breadth of data underscores Company’s commitment to advancing the treatment of liver disease

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) announced today that 14 abstracts on the Company’s research in liver disease have been accepted for presentation at The International Liver Congress™ 2013, the 48th annual meeting of the European Association for the Study of the Liver (EASL), in Amsterdam, April 24 – 28.

Key presentations include:

- New Phase 2 data on an investigational triple direct-acting antiviral (DAA) regimen of daclatasvir (NS5A replication complex inhibitor), asunaprevir (NS3 protease inhibitor) and BMS-791325 (NS5B non-nucleotide polymerase inhibitor) in patients with hepatitis C (HCV) genotypes 1a and 1b. The regimen is being studied as a potential interferon alfa-, ribavirin- and ritonavir-free treatment option to avoid the tolerability and drug-drug interaction profiles of these medicines. These triple DAA data will be highlighted in the official ILC Press Conference on April 24.
- An analysis of all available safety data on 1,100 patients who received daclatasvir plus interferon alfa and ribavirin in Phase 2 studies. These data support the ongoing Phase 3 development program for daclatasvir and further studies of daclatasvir as a component of DAA-based HCV treatment regimens.
- A characterization of ALT flares observed in hepatitis B (HBV) treatment with the investigational interferon Lambda vs. alfa interferon, reflecting differing profiles for the two compounds. Lambda is being developed as a potential alternative for alfa wherever interferon is used in the treatment of either HCV or HBV.
- An analysis of sustained virologic response with daclatasvir plus sofosbuvir, with or without ribavirin, in patients with HCV genotype 1 who previously failed telaprevir or boceprevir.

“Bristol-Myers Squibb has a longstanding commitment to viral hepatitis and has been at the forefront of the evolving science in both hepatitis B and C,” said Brian Daniels, MD, senior vice president, Global Development and Medical Affairs, Research and Development, Bristol-Myers Squibb. “The data we are presenting at the International Liver Congress demonstrate our continued advancement of research to address unmet medical needs, through the development of regimens for personalized hepatitis C treatment and increasing options to treat hepatitis B.”

Bristol-Myers Squibb is studying a portfolio of compounds that has the potential to address unmet medical needs for patients with liver disease, including the investigational compounds daclatasvir, asunaprevir and BMS-791325 for HCV, and Lambda for HCV and HBV. In addition to these compounds, the Company’s medicine BARACLUDE® (entecavir) is approved for the treatment of chronic hepatitis B (CHB) in adults with evidence of active viral replication and either evidence of persistent elevations in aminotransferases (ALT or AST), or histologically active disease.

The complete list of Bristol-Myers Squibb data presentations is below. Abstracts can be accessed on the ILC/EASL website at http://www.easl.eu/_the-international-liver-congress/general-information.
**Hepatitis C: Direct-Acting Antiviral Data**

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<tbody>
<tr>
<td>Synergistic Interactions of HCV NS5A replication Complex Inhibitors Sensitize Resistant Variants and Enhance the Efficacy of Daclatasvir (DCV, BMS-790052) In Vitro and In Vivo</td>
<td>April 25</td>
<td>12:15 – 1:30 pm</td>
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<td>Asunaprevir with Peginterferon and Ribavirin in Treatment-Naïve Patients with Genotype –1 or -4 Chronic Hepatitis C: SVR24 Results From a Randomized Phase 2b Study (AI447016)</td>
<td>April 25</td>
<td>12:15 – 1:30 pm</td>
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<td>Evaluation of Pharmacokinetic Drug-Drug Interaction (DDI) Between BMS-791325, an NS5B Non-Nucleotide Polymerase Inhibitor, Daclatasvir and Asunaprevir in Triple Combination in HCV Genotype 1-Infected Patients</td>
<td>April 25</td>
<td>12:15 – 1:30 pm</td>
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<tr>
<td>The Effect of Coadministration of the Proton-Pump Inhibitor Omeprazole on the Pharmacokinetics of Daclatasvir in Healthy Subjects</td>
<td>April 26</td>
<td>12:30 – 2:00 pm</td>
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<tr>
<td>Exposure-Response Analyses of Asunaprevir in Combination with Daclatasvir ± Peginterferon / Ribavirin Among Patients with Genotype 1 Chronic HCV Infection: Dose Selection for Phase 3 Clinical Trials</td>
<td>April 26</td>
<td>12:30 – 2:00 pm</td>
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<tr>
<td>-Response Analyses of Asunaprevir in Patients with Genotype 1, Chronic HCV Infection: Dose Selection for Phase 3 Clinical Trials</td>
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<tr>
<td>Daclatasvir Combined With Peginterferon Alfa and Ribavirin for 12 or 16 Weeks in Patients With HCV Genotype 2 or 3 Infection: COMMAND GT2/3 Study</td>
<td>April 27</td>
<td>3:30 – 5:30 pm Oral presentation</td>
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<td>Sustained Virologic Response with Daclatasvir Plus Sofosbuvir ± Ribavirin (RBV) In Chronic HCV Genotype (GT) 1-Infected Patients who Previously Failed Telaprevir (TVR) or Boceprevir (BOC)</td>
<td>April 27</td>
<td>3:30 – 5:30 pm Oral presentation</td>
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<tr>
<td>Safety Profile of Daclatasvir in Combination with Peginterferon Alfa and Ribavirin in 1100 Patients with Chronic HCV Infection Treated in Phase 2 Studies</td>
<td>April 27</td>
<td>12:30 – 1:30 pm</td>
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<td>Pre-Existence, Emergence and Persistence of HCV Genotype 4 NS5A Resistance Variants from the Phase 2b COMMAND-1 Study: Daclatasvir Plus Peginterferon-Alfa/Ribavirin in Treatment-Naïve Patients</td>
<td>April 27</td>
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**Hepatitis C: Outcomes Research Data**

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<tr>
<td>Host Genetic Variants Around IL28A/IL28B Associated with HCV-Related Outcomes Based on R.E.V.E.A.L.-HCV Cohort</td>
<td>April 25</td>
<td>12:15 – 1:30 pm</td>
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<td>Genome-Wide Association Study to Identify Potential Single Nucleotide Polymorphisms Associated with Spontaneous Hepatitis C Virus Clearance Among Chronic Hepatitis C Patients</td>
<td>April 25</td>
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**Hepatitis B: Peginterferon Lambda-1a Data**

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<tr>
<td>ALT Flares During Treatment With Peginterferon Lambda or Peginterferon Alfa in Patients with HBeAg-Positive Chronic Hepatitis B Infection (CHB)</td>
<td>April 26</td>
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**Hepatitis B: BARACLUDE® (entecavir) Data**

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<td>Impact of Entecavir Versus Lamivudine on Hepatic Covalently Closed-Circular DNA and Total Hepatic HBV DNA in Nucleoside-Naïve HBeAg Positive Chronic Hepatitis B Patients</td>
<td>April 26</td>
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**INDICATION and IMPORTANT SAFETY INFORMATION about BARACLUDE® (entecavir) Tablets:**

**INDICATION**

BARACLUDE is indicated for the treatment of chronic hepatitis B virus (HBV) infection in adults with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease.

The following points should be considered when initiating BARACLUDE:

- This indication is based on histologic, virologic, biochemical, and serologic responses in nucleoside-treatment-naïve and lamivudine-resistant adult subjects with HBeAg-positive or HBeAg-negative chronic HBV infection and compensated liver disease.
Virologic, biochemical, serologic, and safety data are available from a controlled study in adult subjects with chronic HBV infection and decompensated liver disease.

Virologic, biochemical, serologic, and safety data are available for a limited number of adult subjects with HIV/HBV co-infection who have received prior lamivudine therapy.

**IMPORTANT SAFETY INFORMATION**

**WARNINGS: SEVERE ACUTE EXACERBATIONS OF HEPATITIS B, PATIENTS CO-INFECTED WITH HIV AND HBV, and LACTIC ACIDOSIS AND HEPATOMEGALY**

- Severe acute exacerbations of hepatitis B have been reported in patients who have discontinued anti-hepatitis B therapy, including entecavir. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who discontinue anti-hepatitis B therapy. If appropriate, initiation of anti-hepatitis B therapy may be warranted.

- Limited clinical experience suggests there is a potential for the development of resistance to HIV (human immunodeficiency virus) nucleoside reverse transcriptase inhibitors if BARACLUDE (entecavir) is used to treat chronic HBV infection in patients with HIV infection that is not being treated. Therapy with BARACLUDE is not recommended for HIV/HBV co-infected patients who are not also receiving highly active antiretroviral therapy (HAART).

- Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues, alone or in combination with antiretrovirals.

**Warnings and Precautions**

- Before initiating BARACLUDE® (entecavir) therapy, HIV antibody testing should be offered to all patients. BARACLUDE has not been studied as a treatment for HIV infection and is not recommended for this use.

- Lactic acidosis with BARACLUDE use has been reported, often in association with hepatic decompensation, other serious medical conditions, or drug exposures. Patients with decompensated liver disease may be at higher risk for lactic acidosis. BARACLUDE should be suspended in any patient who develops clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity.

**Adverse Reactions**

- In clinical trials in patients with compensated liver disease, the most common (≥3%) adverse reactions of any severity with at least a possible relation to study drug for BARACLUDE-treated subjects were headache, fatigue, dizziness, and nausea. In these trials, the most common adverse reactions of moderate to severe intensity (grades 2-4) were diarrhea, dyspepsia, nausea, vomiting, fatigue, headache, dizziness, somnolence, and insomnia.

- In the decompensated liver disease trial, the most common adverse reactions of any severity among patients treated with BARACLUDE, regardless of causality, included: peripheral edema (16%), ascites (15%), pyrexia (14%), hepatic encephalopathy (10%), and upper respiratory infection (10%). In this trial, 18% (18/102) of BARACLUDE (entecavir) patients and 20% (18/89) of adefovir patients died during the first 48 weeks of therapy. The majority of those deaths were due to liver related causes.

**Drug Interactions**

BARACLUDE is primarily eliminated by the kidneys, therefore coadministration of BARACLUDE with drugs that reduce renal function or compete for active tubular secretion may increase serum concentrations of either entecavir or the coadministered drug. Patients should be monitored closely when receiving BARACLUDE® (entecavir) with other renally-eliminated drugs.

**Pregnancy and Nursing Mothers**

- There are no adequate and well-controlled studies of BARACLUDE in pregnant women. BARACLUDE should be used during pregnancy only if clearly needed and after careful consideration of the risks and benefits.

- There are no studies on the effect of BARACLUDE on transmission of HBV from mother to infant. Therefore, appropriate interventions should be used to prevent neonatal acquisition of HBV.

- It is not known whether BARACLUDE is excreted into human milk; however, many drugs are excreted into breast milk. Due to the potential for serious adverse reactions in nursing infants from BARACLUDE, risks and benefits should be considered when deciding whether to discontinue breast-feeding or discontinue BARACLUDE in nursing women.

**Pediatric Use**

- Safety and effectiveness of BARACLUDE in pediatric patients below the age of 16 years have not been established.

**Renal Impairment**

- Dosage adjustment of BARACLUDE is recommended for patients with a creatinine clearance <50 mL/min, including those on hemodialysis or continuous ambulatory peritoneal dialysis.

**Liver Transplant Recipients**

- Renal function must be carefully monitored both before and during treatment with BARACLUDE in a liver transplant recipient who has received or is receiving an immunosuppressant that may affect renal function, such as cyclosporine or tacrolimus.
**Dosage and Administration**

BARACLUDE® (entecavir) should be administered on an empty stomach (at least 2 hours after a meal and at least 2 hours before the next meal).

The recommended dose of BARACLUDE:

- in nucleoside-naïve adults and adolescents (16+ yrs) with compensated liver disease is 0.5 mg once daily
- in adults and adolescents (16+ yrs) with compensated liver disease, and refractory to lamivudine or with known lamivudine or telbivudine resistance mutations (rtM204I/V with or without rtL180M, rtL80I/V, or rtV173L) is 1 mg once daily
- in adults with decompensated liver disease is 1 mg once daily

The optimal duration of treatment with BARACLUDE for patients with chronic HBV infection and the relationship between treatment and long-term outcomes such as cirrhosis and hepatocellular carcinoma are unknown.

**Additional Information**

BARACLUDE is not a cure for HBV. Patients should be advised that treatment with BARACLUDE has not been shown to reduce the risk of transmission of HBV to others through sexual contact or blood contamination.

Please see accompanying Full Prescribing Information, including Boxed WARNINGS, or click here.

**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](http://www.bms.com) or follow us on Twitter at [http://twitter.com/bmsnews](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 product development. 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 the clinical trials of these compounds will support regulatory filings, or that the compounds will receive regulatory approvals 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, 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.

**BARACLUDE® (entecavir) is a registered trademark of Bristol-Myers Squibb.**

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English

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**Ticker Slug:**

Ticker: BMY
Exchange: NYSE
