Bristol-Myers Squibb to Present New Data Demonstrating Company’s Commitment to Research and Development in Liver Disease at The International Liver CongressTM / European Association for the Study of the Liver (EASL) Annual Meeting

Release Date: Wednesday, April 4, 2012 10:44 am EDT

Terms: R&D News

Dateline City: PRINCETON, N.J.

First Report of SVR4 Data from the study of daclatasvir (BMS-790052) plus GS-7977 +/-ribavirin in treatment-naïve patients with chronic hepatitis C genotype 1, 2, or 3, during a late breaker poster presentation

Oral presentations on hepatitis C investigational compounds daclatasvir (BMS-790052), asunaprevir (BMS-650032), and peginterferon lambda-1a (Lambda) demonstrate advancement of robust pipeline

Breadth of data highlights Company’s commitment to pursuing research that aims to improve the management of liver disease

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) announced today that 20 abstracts on the Company’s research in liver disease have been accepted for presentation at The International Liver Congress™ 2012, the 47th annual meeting of the European Association for the Study of the Liver (EASL), in Barcelona, April 18 – 22. 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, Lambda, BMS-791325, and BMS-986094 (INX-189) for hepatitis C (HCV); brivanib for hepatocellular carcinoma (HCC); and BARACLUDE® (entecavir). BARACLUDE is currently indicated 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.

Key presentations include one late breaker poster presentation and two oral presentations of Phase II data on the Company’s investigational HCV direct-acting antivirals (DAAs) and Lambda:

- A late breaker presentation on the first report of SVR4 results from a Phase II study of the direct-acting antiviral daclatasvir (NS5A Inhibitor) and GS-7977 (formerly PSI-7977; an NS5B inhibitor), +/-ribavirin, in treatment-naïve patients with chronic HCV genotype 1, 2, or 3
- An oral presentation on dual oral therapy with daclatasvir plus asunaprevir in HCV genotype 1b-infected null responders or ineligible/intolerant to alfa/ribavirin
- The first report of SVR24 results from the EMERGE Phase IIb study peginterferon Lambda-1a (Lambda) compared to peginterferon alfa-2a (alfa) in treatment-naïve patients with HCV genotypes 2 or 3

“Bristol-Myers Squibb is at the forefront of discovering, developing, and delivering potential treatments for diseases of the liver where there remains considerable unmet medical needs,” said Brian Daniels, MD, senior vice president, Global Development and Medical Affairs, Research and Development, Bristol-Myers Squibb. “For example, our goal in hepatitis C is to expand treatment options for patients by developing our portfolio of investigational compounds through multiple treatment approaches. The data we are presenting at the International Liver Congress help to expand our understanding of the potential efficacy and safety profiles of these investigational compounds and support our ongoing Phase III development program in HCV.”

The Company will also present a late-breaker oral presentation on data from the BRISK-PS study of investigational compound
brivanib in patients with HCC who failed or were intolerant to sorafenib and six presentations of outcomes research/real-world data that add to the understanding of the prevalence of and current treatment patterns in HBV, HCV and HCC.

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](http://www.easl.eu/the-international-liver-congress/general-information).

<table>
<thead>
<tr>
<th>Title</th>
<th>Date/Time</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chronic Hepatitis B: BARACLUDE (entecavir) Clinical Data</strong></td>
<td></td>
</tr>
<tr>
<td>Safety and Efficacy of Entecavir in Patients Receiving Liver Transplant Due to Chronic Hepatitis B</td>
<td>April 19, 12:00 – 1:30 p.m.</td>
</tr>
<tr>
<td>The ENTEBE Study: Safety and Efficacy of Entecavir Plus Tenofovir in Adults with Chronic Hepatitis B and Previous Nucleos(t)ide Treatment Failure</td>
<td>April 19, 12:00 – 1:30 p.m.</td>
</tr>
<tr>
<td><strong>Chronic Hepatitis B: Outcomes Research / Real-World Data</strong></td>
<td></td>
</tr>
<tr>
<td>Real-world Data on Treatment Modification from a Long-term Observational Study of Chronic Hepatitis B Patients from 5 European Countries</td>
<td>April 19, 12:00 – 1:30 p.m.</td>
</tr>
<tr>
<td><strong>Hepatitis C: Direct-Acting Antiviral Data</strong></td>
<td></td>
</tr>
<tr>
<td>Confirmation That Quadruple Therapy with Daclatasvir (NS5A Inhibitor), Asunaprevir (NS3 Inhibitor) and Peginterferon/Ribavirin Results in High Rate of SVR4 in HCV Genotype 1 Null Responders</td>
<td>April 19, 12:00 – 1:30 p.m.</td>
</tr>
<tr>
<td>Potent Viral Suppression with All-Oral Combination of Daclatasvir (NS5A Inhibitor) and GS-7977 (NS5B Inhibitor), +/- Ribavirin, in Treatment-Naïve Patients with Chronic HCV GT1, 2, or 3</td>
<td>April 19, 12:00 – 1:30 p.m.</td>
</tr>
<tr>
<td>Dual Oral Therapy With The NS5A Inhibitor Daclatasvir (BMS-790052) and NS3 Protease Inhibitor Asunaprevir (BMS-650032) in HCV Genotype 1b-Infected Null Responders or Ineligible/Intolerant to Peginterferon/Ribavirin</td>
<td>April 19, 4:00 – 6:00 p.m.</td>
</tr>
<tr>
<td>A Description Of Virologic Escape In HCV Genotype 1-Infected Patients Treated with Daclatasvir (BMS-790052) in Combination With Ribavirin and Peginterferon Alfa-2a or Peginterferon Alfa-2b</td>
<td>April 21, 12:30 – 1:30 p.m.</td>
</tr>
<tr>
<td><strong>Hepatitis C: PEG-Interferon Lambda Data</strong></td>
<td></td>
</tr>
<tr>
<td>Peginterferon Lambda-1a (Lambda) Compared to Peginterferon Alfa-2a (Alfa) in Treatment-Naïve Patients with HCV Genotypes (G) 2 or 3: First SVR24 Results From EMERGE Phase IIb</td>
<td>April 19, 4:00 – 6:00 p.m.</td>
</tr>
<tr>
<td>Effect of Pegylated Interferon Lambda-1a on Low Densiy Lipoprotein and Its Association with Virologic Response in Chronic Hepatitis C Patients in A Phase 2b Study</td>
<td>April 21, 12:30 – 1:30 p.m.</td>
</tr>
<tr>
<td>Exposure-Response Analyses of Pegylated Interferon Lambda (Lambda, BMS-914143) in Patients with Chronic HCV Infection: Dose Selection For Phase 3 Clinical Trials</td>
<td>April 21, 12:30 – 1:30 p.m.</td>
</tr>
<tr>
<td><strong>Hepatitis C: Outcomes Research / Real-World Data</strong></td>
<td></td>
</tr>
<tr>
<td>The Effect of Hepatitis C Treatment on Health-Related Quality of Life, Work Productivity, and Healthcare Resource Use Among Patients in Europe</td>
<td>April 21, 12:30 – 1:30 p.m.</td>
</tr>
<tr>
<td>Development and Validation of Prediction Models For Risk of Hepatocellular Carcinoma Among Hepatitis C Virus Infected Patients</td>
<td>April 20, 12:30 – 2:00 p.m.</td>
</tr>
<tr>
<td>Evaluating Optimal Treatment Outcomes of Antiviral Therapy in Hepatitis C For Prior Null Responders in the Era of First Generation Protease Inhibitors</td>
<td>April 20, 12:30 – 2:00 p.m.</td>
</tr>
<tr>
<td><strong>Hepatocellular Carcinoma: Brivanib Data</strong></td>
<td></td>
</tr>
<tr>
<td>Brivanib Versus Placebo In Patients With Advanced Hepatocellular Carcinoma (HCC) Who Failed or Were Intolerant to Sorafenib: Results From The Phase 3 Brisk-PS Study</td>
<td>April 21, 3:30 – 5:30 p.m.</td>
</tr>
<tr>
<td><strong>Hepatocellular Carcinoma: Outcomes Research</strong></td>
<td></td>
</tr>
<tr>
<td>Observations of Hepatocellular Carcinoma (HCC) Management Patterns from the Global HCC BRIDGE Study: Second Interim Analysis of the European (EU) Cohort</td>
<td>April 20, 12:30 – 2:00 p.m.</td>
</tr>
<tr>
<td>Observed Patterns of Systemic Therapy Use in Hepatocellular Carcinoma (HCC) Patients from the Multinational HCC BRIDGE Study: Results of a Second Interim Analysis</td>
<td>April 20, 12:30 – 2:00 p.m.</td>
</tr>
</tbody>
</table>
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 coinfection 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 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 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.

- The safety and efficacy of BARACLUDE (entecavir) in liver transplant recipients are unknown. 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 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 compounds described in this release will receive regulatory approvals or, if approved, that they will become commercially successful. 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, 2011, 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.

Language:

English

Contact:

Bristol-Myers Squibb Company
Media:
Cristi Barnett, 609-252-6028
cristi.barnett@bms.com
or
Investors:
John Elicker, 609-252-4611
john.elicker@bms.com

Ticker Slug:

Ticker: BMY
Exchange: NYSE