BARACLUDE (Entecavir) Data Continue to Demonstrate Low Incidence of Resistance Through Five Years of Treatment In Nucleoside-Naïve Chronic Hepatitis B Patients

Data Indicate Pre-existing Lamivudine Resistance Predisposes Patients to Higher Rates of BARACLUDE Resistance

Princeton, NJ (PRWEB) March 24, 2008 -- New BARACLUDE® (entecavir) data presented today demonstrated a continued low incidence of resistance in nucleoside-naïve patients through five years of treatment. In the nucleoside-naïve chronic hepatitis B patients analyzed, no additional patient developed resistance in the fifth year (n=108). Through five years of treatment, the cumulative probability of developing mutations in the virus that confer resistance to BARACLUDE (also called genotypic resistance) was 1.2 percent. Bristol-Myers Squibb Company (NYSE: BMY) announced the results at the 18th Conference of the Asia-Pacific Association for the Study of the Liver in Seoul, Korea.

In lamivudine-refractory patients who received BARACLUDE after treatment with lamivudine failed, the cumulative probability of genotypic BARACLUDE resistance was 51 percent through the fifth year. This finding is consistent with prior observations that the pre-existence of lamivudine-resistant mutations results in an increase in the rate of BARACLUDE resistance.

"Many chronic hepatitis B patients require long-term treatment. Unfortunately, the initial benefits of therapy can be lost after the development of resistance. These five-year BARACLUDE data that demonstrate long-term minimal resistance at 1.2 percent in nucleoside-naïve patients can be of great importance for patients," said Professor Ching-Lung Lai, Chief, Division of Gastroenterology and Hepatology, University of Hong Kong.

Drug resistance occurs when the hepatitis B virus (HBV) mutates, thereby avoiding the effects of the medication. This can decrease the efficacy of the current medication and may compromise future treatment options. To date, studies have shown that multiple mutations are required to develop BARACLUDE® (entecavir) resistance.

"These long-term BARACLUDE data continue to support the observations seen in the first years of treatment and are reflective of BARACLUDE's high genetic barrier to resistance," said Helena Brett-Smith, M.D., Group Director of Clinical Research at Bristol-Myers Squibb. "More importantly, we believe the data support BARACLUDE as an important initial treatment choice for chronic hepatitis B, which is a disease that results in a large global health burden."

About the Analysis
More than 700 patients across six studies initiated therapy on BARACLUDE and were monitored for treatment response and resistance.

The year five analysis expands upon previous analyses, adding in information on patients who received treatment with BARACLUDE during the fifth year of follow-up (n=108 for patients in nucleoside-naïve studies and n=33 for patients in lamivudine-refractory studies).
In this comprehensive analysis, all patients enrolled in Bristol-Myers Squibb clinical trials ETV-014, -015, -022, -027, -026 and -901 who experienced a virologic breakthrough1 or whose virus had not yet reached undetectable levels2 at weeks 48, 96, 144, 192, 240 or end of dosing, were sequenced to determine if any changes occurred in the genetic code of the virus that would result in resistance or loss of effectiveness of BARACLUDE.

Nucleoside-naïve patients in this analysis were initially treated with BARACLUDE0.5 mg in studies ETV-022 and -027 and continued treatment with BARACLUDE 1 mg by enrolling in study ETV-901 with a treatment gap of less than or equal to 35 days. Lamivudine-refractory patients in this analysis initiated therapy on BARACLUDE 1 mg in studies ETV-014, -015, and -026 and continued treatment in study ETV-901 with a treatment gap of less than or equal to 35 days.

1 Virologic breakthrough is defined as a greater than or equal to 1 log increase in HBV DNA from nadir, as measured by the polymerase chain reaction or PCR assay.
2 Undetectable viral load is defined as HBV DNA levels less than 300 copies/mL, as measured by PCR assay.

Viral load reduction in chronic hepatitis B patients treated with BARACLUDE® (entecavir) in nucleoside-naïve and lamivudine-refractory studies was also evaluated.

Data Results
Results from these studies prior to this year five analysis were previously announced on April 14, 2007.

Nucleoside-naïve data
• The incidence of BARACLUDE resistance in patients in nucleoside-naïve studies over time is low, with a cumulative probability of genotypic BARACLUDE resistance of 1.2 percent through five years.
• No nucleoside-naïve patient developed resistance (n=108) in year five.
• 93 percent of the nucleoside-naïve patients taking BARACLUDE were able to achieve and maintain an undetectable viral load (HBV DNA < 300 copies/mL) through year five (n=108).

Lamivudine-refractory data
• The results in lamivudine-refractory patients in years one through five were consistent with the finding that the pre-existence of lamivudine-resistant substitutions resulted in an increase in the emergence of BARACLUDE resistance, with a cumulative probability of genotypic resistance of 51 percent through five years.
• In year five, 43 percent of lamivudine-refractory patients had virologic breakthrough with BARACLUDE resistance (n=33).
• During this resistance monitoring program, 72 of the 187 lamivudine-refractory patients achieved undetectable viral load (< 300 copies/mL) and of these, one patient developed virologic breakthrough due to BARACLUDE resistance.

About BARACLUDE® (entecavir)
Discovered at Bristol-Myers Squibb, BARACLUDE® (entecavir) is a nucleoside analogue indicated for use in adults with chronic hepatitis B infection with compensated liver disease and: evidence of active viral replication; evidence of persistent elevations of the blood levels of aminotransferases, a marker for liver disease; and active liver disease as determined by biopsy.

BARACLUDE has been approved in more than 60 countries and regions around the world. Bristol-Myers Squibb is a global pharmaceutical and related health care products company whose mission is to...

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For full prescribing information for BARACLUDE, please consult the Summary of Product Characteristics.

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