BARACLUDE® (entecavir) Therapy Resulted in Undetectable Levels of Hepatitis B Virus in Cohort of Patients Who Re-Started Treatment

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93 Percent of Nucleoside-Naive Chronic Hepatitis B e-Antigen (HBeAg)-Negative Patients Achieved Undetectable Viral Load by Week 48 of Re-Treatment

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE: BMY) today announced data from a cohort of nucleoside-naive HBeAg-negative chronic hepatitis B patients (ETV-027/901, n=99). These data showed that patients who experienced recurrent levels of hepatitis B virus in the blood after interruption of treatment with BARACLUDE® (entecavir) achieved viral suppression and liver enzyme (ALT) normalization when re-treated for 48 weeks with BARACLUDE. The study results were presented at the 42nd Annual Meeting of the European Association for the Study of Liver Diseases (EASL) in Barcelona, Spain.

In this cohort, 93 percent of patients who were re-treated with BARACLUDE had undetectable viral load - the level of the hepatitis B virus in the blood - (HBV DNA <300 copies/mL, measured by a common assay - polymerase chain reaction or PCR) and 83 percent achieved liver enzyme (ALT) normalization after 48 weeks of therapy.

"This study showed that when treated again with BARACLUDE for 48 weeks, patients achieved responses similar to those seen prior to treatment interruption, with safety results consistent with previously reported experience," said Hakan Senturk, MD, of the Ist.Univ.Cerrahpasa Tip Fak, Istanbul, Turkey.

No deaths or treatment discontinuations due to adverse events were reported in this cohort. The most common adverse events occurring in greater than 10 percent of patients were abdominal pain, fatigue, upper respiratory tract infection, nasopharyngitis, increased ALT, arthralgia, and headache.

About the Nucleoside-Naive HBeAg-Negative BARACLUDE® (entecavir) Re-Treatment Cohort

This analysis evaluated BARACLUDE® (entecavir) in nucleoside-naive chronic HBeAg-negative patients who discontinued study therapy in ETV-027, and subsequently restarted treatment in rollover study ETV-901, with a greater than 60 day gap between end of dosing in study ETV-027 and start of treatment in study ETV-901.

* ETV-027 compared 0.5 mg of BARACLUDE vs. 100 mg of lamivudine in nucleoside-naive chronic HBeAg-negative chronic hepatitis B patients.

* Rollover study ETV-901 was established as an open-label, follow-up protocol for patients in phase II and III studies of BARACLUDE.

* Due to ongoing blinding of study ETV-027, most patients retreated in ETV-901 initially received a combination of 1 mg of BARACLUDE plus 100 mg of lamivudine, and were subsequently switched to 1 mg of BARACLUDE monotherapy.

The analysis cohort was defined regardless of treatment response at the end of dosing in study ETV-027, and independent of virologic or ALT measurements at the start of dosing in study ETV-901. During off-treatment follow-up, the majority of patients had recurrent levels of hepatitis B virus in the blood (viremia) and increases in ALT.

Data Results

At the end of dosing for study ETV-027:

* 94 percent (n=93/99) of the re-treatment cohort had undetectable viral load

* 78 percent (n=77/99) had ALT normalization

At entry into ETV-901:

* Four percent (n=4/99) of patients had undetectable viral load

* Eight percent (n=8/97) of patients had ALT normalization
Following re-treatment in study ETV-901:

* 93 percent (n=82/88) of patients had undetectable viral load (HBV DNA <300 copies/mL) by week 48 of re-treatment with BARACLUDE

* 83 percent (n=79/95) of patients had ALT normalization (ALT less than or equal to 1 times the upper limit of normal) by week 48 of re-treatment BARACLUDE

Adverse events in study ETV-027/901 re-treatment cohort:

* 67 percent (n=66/99) of patients experienced an adverse event. The most common adverse events occurring in greater than ten percent of patients were abdominal pain, fatigue, upper respiratory tract infection, nasopharyngitis, increased ALT, arthralgia, and headache.

* There were no deaths or treatment discontinuations due to adverse events.

* Nine percent (n=9/99) of patients experienced a serious adverse event. Serious adverse events included ALT elevation or hepatitis exacerbation (4), bilirubin elevation (1), inguinal hernia (1), sialoadenitis (1), thrombocytopenic purpura (1), groin pain (1), macular edema (1), urinary incontinence (1) and cholelithiasis (1). Two of these events, hepatitis exacerbation (1) and thrombocytopenia (1), were considered possibly related to treatment by the investigator.

* Five percent (n=5/99) of patients experienced an ALT flare on treatment (ALT > 2 times baseline and >10 times the upper level of normal)

About BARACLUDE® (entecavir)

Discovered at Bristol-Myers Squibb, BARACLUDE® (entecavir) is a nucleoside analogue indicated for the treatment of chronic hepatitis B virus infection in adults with evidence of active viral replication with either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease. BARACLUDE has been approved in more than 60 countries and regions around the world.

Important Information About BARACLUDE® (entecavir) 0.5mg/1mg Tablets

BARACLUDE® (entecavir) is a prescription medicine used for chronic infection with hepatitis B virus (HBV) in adults where the virus is multiplying and damaging the liver. BARACLUDE does not cure HBV or stop the spread of HBV to others.

People should not take BARACLUDE if they are allergic to it or any of its ingredients. BARACLUDE has not been studied in children and is not recommended for anyone less than 16 years of age.

People taking BARACLUDE® (entecavir) should tell their healthcare provider right away if they feel very weak or tired, have unusual muscle pain, have trouble breathing, have stomach pain with nausea and vomiting, feel cold - especially in their arms and legs, feel dizzy or lightheaded, or have a fast or irregular heartbeat, as they may be signs of a serious condition called lactic acidosis (buildup of an acid in the blood).

Lactic acidosis is a medical emergency and must be treated in the hospital. Some people who have taken medicines like BARACLUDE have developed serious liver problems called hepatotoxicity. This may occur with liver enlargement (hepatomegaly) and fat in the liver (steatosis).

People should call their healthcare provider right away if they get any of the following signs of liver problems: yellowing (jaundice) of the skin or the white part of the eyes, darkening of the urine, lightening in the color of bowel movements (stools), not feeling like eating food for several days or longer, feeling sick to the stomach (nausea), or having lower stomach pain. Lactic acidosis and hepatotoxicity have happened in some people taking medicines like BARACLUDE.

In some people, hepatitis B symptoms may get worse or become very serious when they stop taking BARACLUDE. People should not stop BARACLUDE without talking to their healthcare provider. Healthcare providers will need to follow their patients and do blood tests to check the liver when BARACLUDE is stopped. People should tell their healthcare provider if they have or develop kidney problems because their healthcare provider may want to do tests to see if a lower dose is needed or a different dose schedule.

Because BARACLUDE is removed from the body through the kidneys, a lower dose or a different dose schedule may be required. Healthcare providers may want to perform tests to determine whether a patient needs a lower dose or should take BARACLUDE less often than once a day.

It is not known if BARACLUDE is safe to use during pregnancy. It is not known if BARACLUDE helps to prevent a pregnant mother from passing HBV to her baby. A pregnant woman and her healthcare provider will need to decide if BARACLUDE is right for her. A woman should not breastfeed if she is taking BARACLUDE.

People should discuss with their healthcare provider all prescription and non-prescription medicines, vitamins, herbal supplements, and other health preparations they are taking or plan to take. BARACLUDE® (entecavir) may interact with medicines that leave the body through the kidneys. The most common side effects of BARACLUDE in clinical studies were headache, tiredness, dizziness, and nausea.

This list of side effects is not complete at this time because BARACLUDE is still under study. People should report any new or continuing symptom to their healthcare provider. BARACLUDE should be taken once daily on an empty stomach (at least two hours after a meal and two hours before the next meal). To learn more about BARACLUDE and for Full Prescribing Information, including boxed WARNINGS, please visit http://www.bms.com/.

Bristol-Myers Squibb is a global pharmaceutical and related health care products company whose mission is to extend and enhance human life.
BARADEFINE® (entecavir) is a trademark of Bristol-Myers Squibb Company.

Full prescribing information for BARADEFINE, including boxed WARNINGS, is available at http://www.bms.com/.

Web site: http://www.bms.com/

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