Abbott and Enanta Present Positive Initial Results from Phase 2 Study of ABT-450/R for Treatment of Hepatitis C

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ABBOTT PARK, Ill., and WATERTOWN, Mass., Nov. 1, 2010 —Abbott and Enanta Pharmaceuticals today announced positive results from a Phase 2 study of ABT-450/r, an investigational, oral protease inhibitor being developed for the treatment of hepatitis C (HCV) infection. Initial 3-day and 4-week results suggest that ABT-450/r (ABT-450 with 100mg of ritonavir to support once-daily dosing) demonstrates potent antiviral activity in treatment-naïve adults. Results show that more than 90 percent of patients (21 of 23) on study drug achieved HCV-RNA levels <25 IU/mL at four weeks. Results were presented today at the American Association for the Study of Liver Disease annual meeting in Boston.

Key findings:

- After three days, treatment with ABT-450/r alone resulted in statistically significant, 4-log mean reductions of HCV RNA, across the three dose ranges of ABT-450 (50mg, 100mg, 200mg, once-daily dosing) compared to placebo
- At week four, 91.3 percent (21 of 23) of patients receiving ABT-450/r in combination with standard of care (SOC) – pegylated alpha interferon and ribavirin (pegIFN/RBV) – achieved HCV-RNA <25 IU/ml
- Safety appears consistent to that expected with SOC

"In spite of the progress that has been made in HCV treatment, limitations in efficacy remain with the current standard of care," Fred Poordad, M.D., chief of hepatology at the Liver Disease and Transplant Center at Cedars-Sinai Medical Center in Los Angeles, and one of the investigators for the study. "The initial results of ABT-450/r in patients with HCV suggest that ABT-450/r has favorable potency in the most common HCV genotype and that ABT-450/r could be an important element in a combination direct-acting antiviral regimen for treatment of HCV."

"Abbott has focused its antiviral research expertise on finding new treatment options for HCV-infected patients that could transform current therapy – by shortening the duration of treatment and increasing cure rates," said Scott Brun, M.D., divisional vice president, infectious disease development, Abbott. "We continue to explore the potential for use of ABT-450/r in a variety of combination regimens."

"We are very encouraged by the 3-day monotherapy and 4-week rapid virologic response results for ABT-450 and we look forward to further clinical results from the program," said Jay Luly, Ph.D, president and chief executive officer, Enanta Pharmaceuticals. "This data is an important step in our HCV program, and for advancing our broader vision to improve patient care in this field."

Study Objectives and Design

The objectives of the 48-week Phase 2 study are to assess the safety, tolerability, pharmacokinetics, and antiviral activity of multiple dose strengths of ABT-450/r in treatment-naïve adults infected with HCV genotype 1, which is the most common and difficult to treat form of the infection in the developed world. Trial endpoints include early virologic response and rapid virologic response. Initial antiviral activity was evaluated via a 3-day treatment period during which ABT-450/r was administered alone. Subsequently, ABT-450/r was administered with pegIFN/RBV (SOC) for 12 weeks, followed by treatment with SOC alone for an additional 36 weeks. Participants are then monitored post therapy for 24 weeks for sustained virologic response.

ABT-450 was discovered as part of an alliance between Abbott and Enanta and is being developed with low-dose ritonavir, which enhances the pharmacokinetic properties of ABT-450, allowing for once-daily dosing. This Phase 2 study also evaluated ABT-333 and ABT-072, two of Abbott's internally discovered compounds that are part of the company's ongoing non-nucleoside polymerase inhibitor development program. The study findings for these two compounds have been submitted for presentation at a future scientific meeting.

About the Hepatitis C Virus

Hepatitis C is a liver disease affecting more than 180 million people worldwide. The virus is primarily spread through direct contact with the blood of an infected person. HCV increases a person's risk of developing chronic liver disease, cirrhosis, liver cancer and death.

Liver disease associated with HCV infection is growing rapidly, and current therapies only cure about half of patients with the genotype 1 form of the virus. Specifically targeted antiviral therapies for HCV, such as protease inhibitors and non-nucleoside polymerase inhibitors, may have the potential to increase the proportion of patients in whom the virus can be eradicated.

About Ritonavir

NORVIR is in a class of medicines called the HIV protease (PRO-tee-ase) inhibitors. NORVIR is used in combination with other anti-HIV medicines to treat people with human immunodeficiency virus (HIV) infection. NORVIR is for adults and for children age greater than 1 month and older.

NORVIR does not cure HIV infection or AIDS and does not reduce the risk of passing HIV to others. People taking NORVIR may still get opportunistic infections or other conditions that happen with HIV infection. Some of these conditions are pneumonia, herpes virus infections, and Mycobacterium avium complex (MAC) infections.

People should not take NORVIR with certain medicines, as these can cause serious or life-threatening problems such as irregular heartbeat, breathing difficulties, or excessive sleepiness. People should not take NORVIR if they have had a serious allergic reaction to any of its ingredients. Some patients taking NORVIR may develop liver and pancreas problems, which can cause death. Patients may develop large increases in triglycerides and cholesterol, diabetes, high blood sugar, changes in body fat, increased bleeding in people with hemophilia, allergic reactions, and/or changes in heart rhythm. People may develop signs and symptoms of infections that they already have after starting anti-HIV medicines.

Please see the Important Safety Information below for more details, including the potential for serious or life-threatening drug interactions.

Please click here for Norvir full Prescribing Information.

Globally, prescribing information varies; please refer to your individual country's full Prescribing Information for complete information.

About Enanta

Enanta Pharmaceuticals is a research and development company that uses its novel chemistry approach and drug discovery capabilities to create best in class small molecule drugs in the infectious disease field. Enanta is developing novel protease, NS5A, polymerase, and cyclophilin-based inhibitors targeted against the Hepatitis C virus (HCV). Additionally, the Company has created a new class of macrolide antibiotics, called Bicyclolides, which overcomes bacterial resistance. Antibacterial focus areas include superbugs, respiratory tract infections, and intravenous and oral treatments for hospital and community MRSA. Enanta is a privately held company headquartered in Watertown, Mass. Enanta's news releases and other information are available on the company's web site at www.enanta.com.

About Abbott

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacturing and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs nearly 90,000 people and markets its products in more than 130 countries. Abbott's news releases and other information are available on the company's Web site at www.abbott.com.

Important Safety Information about Ritonavir

People who have had a serious allergic reaction to NORVIR or any of its ingredients should not take NORVIR. Allergic reactions ranging from hives, asthma, severe breathing issues and mild to severe skin reactions have occurred.

Drug Interactions:

The below list of drug interactions is not complete. Before people take NORVIR, they must tell their doctor about all the medicines they are taking or are planning to take. These include other prescription and non-prescription medicines, and herbal supplements.

People should not take the following medicines with NORVIR because they can cause serious or life-threatening problems such as irregular heartbeat, breathing difficulties or excessive sleepiness: Cordarone ® (amiodarone); ergotamine, ergonovine, methylergonovine, and dihydroergotamine such as Cafergot ® , Migranal ® , D.H.E. 45 ® and others; Halcion ® (triazolam); Orap ® (pimozide); Propulsid ® (cisapride); quinidine, also known as Quinaglute ® , Cardioquin ® , Quinidex ® and others; Revatio ® (sildenafil) only when used for the treatment of pulmonary arterial hypertension; Rythmol ® (propafenone); Tambocor ® (flecainide); Uroxatral ® (alfuzosin hydrochloride); Vascor ® (bepridil); Versed ® (oral midazolam); and Vfend ® (voriconazole).

People should not take NORVIR with St. John's wort (Hypericum perforatum) as this may decrease NORVIR levels and lead to increased viral load and possible resistance to NORVIR or other antiretroviral medicines.

People should not take NORVIR with Mevacor ® (lovastatin) or Zocor ® (simvastatin) because of possible serious reactions. There is an increased risk of drug interactions between NORVIR and Lipitor ® (atorvastatin) and Crestor ® (rosuvastatin); people should talk to their doctor before they take any of these cholesterol-lowering medicines with NORVIR.

For people taking Viagra ® (sildenafil), Cialis ® (tadalafil), or Levitra ® (vardenafil) with NORVIR, their doctor may lower their dose of these medicines because they may be at risk of side effects such as low blood pressure, visual changes, and penile erection lasting more than 4 hours. People should tell their doctor right away if they experience any of these side effects.

If people are taking Adcirca ® (tadalafil) for pulmonary arterial hypertension, their doctor may change their dose of this medicine.

Women taking oral contraceptives ("the pill") or using the contraceptive patch to prevent pregnancy should use a different type of contraception since NORVIR may reduce the effectiveness of oral or patch contraceptives.

For people taking Mycobutin ® (rifabutin), their doctor will lower the dose of Mycobutin.

For people taking Colcrys ® (colchicine) or Tracleer ® (bosentan), their doctor will tell them what dose to use.

NORVIR oral solution contains alcohol. People should talk with their doctor if they are taking or planning to take Flagyl ® (metronidazole) or Antabuse ® (disulfiram). Severe nausea and vomiting can occur.

Rifampin, also known as Rimactane ® , Rifadin ® , Rifater ® , or Rifamate ® , may reduce blood levels of NORVIR. People should tell their doctor if they are taking rifampin.

Rifampin and saquinavir should not be taken together with NORVIR. People should tell their doctor if they are taking rifampin and saquinavir. People taking or about to begin using inhaled Flonase ® (fluticasone propionate), Serevent ® (salmeterol), or Advair ® (salmeterol in combination with fluticasone propionate) should talk to their doctor about problems these medicines may cause when taken with NORVIR. Their doctor may choose not to keep them on inhaled Flonase, Serevent, or Advair.

Side Effects (This list is not complete):

Blood tests in patients taking NORVIR may show possible liver problems. People with liver disease such as hepatitis B and C who take NORVIR may

have worsening liver disease. Liver problems, including death, have occurred in people who take NORVIR and in people taking Aptivus ® (tipranavir) with NORVIR. People should tell their doctor right away if they have any of the following signs and symptoms: loss of appetite, yellowing of skin or eyes (jaundice), dark-colored urine, pale-colored stools, itchy skin and/or stomach area (abdominal) pain.

Pancreas problems (pancreatitis), which may cause death, have been reported in some people taking NORVIR. People should tell their doctor if they have nausea, vomiting or abdominal pain as these may be signs of pancreatitis.

Large increases in triglycerides and cholesterol have occurred in some people taking NORVIR. The long-term chance of getting complications such as heart attacks or stroke due to increases in triglycerides and cholesterol caused by protease inhibitors is not known at this time.

Diabetes and high blood sugar (hyperglycemia), changes in body fat, and increased bleeding in people with hemophilia have occurred in some people taking protease inhibitors including NORVIR. People should tell their doctor if they have diabetes or an increase in thirst or urinate often. The cause and long-term effects of body fat changes are not known at this time.

Changes in the electrocardiogram (EKG) can occur when taking NORVIR. People should consult their physician if they experience dizziness, lightheadedness, fainting spells or abnormal heartbeat. People with heart defects or conduction defects should avoid NORVIR.

Immune reconstitution syndrome may occur after starting anti-HIV medicines, including NORVIR. This happens when people develop signs and symptoms of serious infections they already have or had, which may require additional treatment.

The most commonly reported side effects are feeling weak/tired, nausea, vomiting, diarrhea, loss of appetite, abdominal pain, changes in taste, tingling feeling or numbness (in hands, feet or around the lips), headache, and dizziness.

For women who are pregnant or planning to become pregnant, it is not known if NORVIR can harm their unborn baby. Women taking NORVIR while they are pregnant should talk to their healthcare professional about how they can take part in the Antiretroviral Pregnancy Registry. Mothers taking NORVIR should not breast-feed because they may pass HIV on to their baby, or their baby could experience side effects from NORVIR.

The long-term effects of NORVIR are not known at this time.