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Vertex and Alios BioPharma Begin Clinical Studies of Nucleotide Drug Candidates ALS-2200 and ALS-2158 for the Treatment of Hepatitis C

-Studies to evaluate safety and effects on viral kinetics in people with chronic genotype-1 hepatitis C-

-Data expected in second quarter of 2012 could enable initiation of interferon-free, nucleotide-based combination studies in the second half of 2012-

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) and Alios BioPharma, Inc. today announced the initiation of two clinical studies for the nucleotide analogues ALS-2200 and ALS-2158, which are inhibitors of the hepatitis C NS5B polymerase. The studies will evaluate the safety and tolerability of ALS-2200 and ALS-2158 in healthy volunteers followed by a seven-day evaluation to observe the effects on viral kinetics in people with chronic genotype-1 hepatitis C. Data are expected in the second quarter of 2012, which could enable the initiation of studies to evaluate multiple all-oral, interferon-free combination regimens for chronic hepatitis C in the second half of 2012. Vertex has worldwide development and commercialization rights for ALS-2200 and ALS-2158, which were discovered by Alios BioPharma. Alios and Vertex are jointly conducting the Phase 1 studies announced today.

"These studies are an important step in our ongoing efforts to strengthen our leadership position in hepatitis C by developing all-oral regimens that could further improve the future treatment of this disease," said Peter Mueller, Ph.D., Executive Vice President, Global Research and Development, and Chief Scientific Officer for Vertex. "The studies of ALS-2200 and ALS-2158 announced today are designed to generate data that may provide the opportunity to rapidly advance into Phase 2 development where we could evaluate a number of nucleotide-based regimens beginning in the second half of next year, including regimens with INCIVEK or VX-222."

Study Design

The two Phase 1 studies announced today will be randomized, double-blind, placebo-controlled studies. The primary goals are to evaluate the safety and tolerability of single ascending doses of ALS-2200 and ALS-2158 in healthy volunteers and of multiple ascending doses in people with chronic genotype-1 hepatitis C. A secondary objective will be to evaluate the effects on viral kinetics of ALS-2200 and ALS-2158 during seven days of dosing in people with hepatitis C.

Dosing is now underway for the study of ALS-2200, and dosing is expected to begin next week for the study of ALS-2158. Vertex and Alios BioPharma expect to have complete data, including seven-day viral kinetic data, from each trial in the second quarter of 2012, which could enable the initiation of all-oral, interferon-free Phase 2 combination studies in the second half of 2012. These Phase 2 studies are expected to evaluate combination regimens of ALS-2200 or ALS-2158 with INCIVEK (telaprevir) or VX-222, potential dual nucleotide regimens and other interferon-free combination regimens that may also include ribavirin. INCIVEK is Vertex's FDA-approved protease inhibitor for chronic genotype-1 hepatitis C, and VX-222 is Vertex's investigational hepatitis C non-nucleoside polymerase inhibitor. The combination studies will be designed to generate sustained viral response (SVR or viral cure) data.

About ALS-2200 and ALS-2158

ALS-2200 and ALS-2158 are highly potent pan-genotypic nucleotide analogues that appear in *in vitro* and non-clinical studies to have a high barrier to drug resistance and the potential to be dosed orally once-daily. Both compounds are designed to inhibit the replication of the hepatitis C virus by acting on the NS5B polymerase. Each compound is structurally distinct and has its own unique mechanism of action, which supports the potential for developing these compounds together as a dual nucleotide regimen and as part of combination therapy regimens, including regimens with INCIVEK™ (telaprevir) and VX-222. Data from *in vitro* studies showed that both ALS-2200 and ALS-2158 had a synergistic effect when combined together and with INCIVEK and VX-222. Additionally, in those *in vitro* studies, both compounds showed antiviral activity across all genotypes, or forms, of the hepatitis C virus, including genotypes more prevalent outside of the United States.

Vertex gained worldwide rights to ALS-2200 and ALS-2158 through an exclusive worldwide licensing agreement signed with Alios BioPharma, Inc. in June 2011. The agreement also includes a research program that will focus on the discovery of additional nucleotide analogues that act on hepatitis C polymerase. Vertex has the option to select additional compounds for

development emerging from the research program.

IMPORTANT SAFETY INFORMATION

Indication

INCIVEK™ (telaprevir) is a prescription medicine used with the medicines peginterferon alfa and ribavirin to treat chronic (lasting a long time) hepatitis C genotype 1 infection in adults with stable liver problems, who have not been treated before or who have failed previous treatment. It is not known if INCIVEK is safe and effective in children under 18 years of age.

Important Safety Information

INCIVEK should always be taken in combination with peginterferon alfa and ribavirin. Ribavirin may cause birth defects or death of an unborn baby. Therefore, a patient should not take INCIVEK combination treatment if she is pregnant or may become pregnant, or if he is a man with a sexual partner who is pregnant. Patients must use two forms of effective birth control during treatment and for the 6 months after treatment with these medicines. Hormonal forms of birth control, including birth control pills, vaginal rings, implants or injections, may not work during treatment with INCIVEK.

INCIVEK and other medicines can affect each other and can also cause side effects that can be serious or life threatening. There are certain medicines patients cannot take with INCIVEK combination treatment. Patients should tell their healthcare providers about all the medicines they take, including prescription and non-prescription medicines, vitamins and herbal supplements.

INCIVEK can cause serious side effects including skin reactions, rash and anemia that can be severe. The most common side effects of INCIVEK include itching, nausea, diarrhea, vomiting, anal or rectal problems, taste changes and tiredness. There are other possible side effects of INCIVEK, and side effects associated with peginterferon alfa and ribavirin also apply to INCIVEK combination treatment. Patients should tell their healthcare providers about any side effect that bothers them or doesn't go away.

Please see full Prescribing Information for INCIVEK including the Medication Guide, available at www.INCIVEK.com.

About Hepatitis C

Hepatitis C is a serious liver disease caused by the hepatitis C virus, which is spread through direct contact with the blood of infected people and ultimately affects the liver.[1] Chronic hepatitis C can lead to serious and life-threatening liver problems, including liver damage, cirrhosis, liver failure or liver cancer.[1] Though many people with hepatitis C may not experience symptoms, others may have symptoms such as fatigue, fever, jaundice and abdominal pain.[1]

Unlike HIV and hepatitis B virus, chronic hepatitis C can be cured.[2] However, approximately 60 percent of people do not achieve SVR,[3,4,5] or viral cure,[6] after treatment with 48 weeks of pegylated-interferon and ribavirin alone. If treatment is not successful and a person does not achieve a viral cure, they remain at an increased risk for progressive liver disease.[7,8]

More than 170 million people worldwide are chronically infected with hepatitis C.[6] In the United States, nearly 4 million people have chronic hepatitis C and 75 percent of them are unaware of their infection.[9] Hepatitis C is four times more prevalent in the United States compared to HIV.[9] The majority of people with hepatitis C in the United States were born between 1946 and 1964, accounting for two of every three people with chronic hepatitis C.[10] Hepatitis C is the leading cause of liver transplantations in the United States and is reported to contribute to 4,600 to 12,000 deaths annually.[11,12] By 2029, total annual medical costs in the United States for people with hepatitis C are expected to more than double, from $30 billion in 2009 to approximately $85 billion.[9]

About Vertex

Vertex creates new possibilities in medicine. Our team discovers, develops and commercializes innovative therapies so people with serious diseases can lead better lives.

Vertex scientists and our collaborators are working on new medicines to cure or significantly advance the treatment of hepatitis C, cystic fibrosis, rheumatoid arthritis, epilepsy and other life-threatening diseases.

Founded more than 20 years ago in Cambridge, MA, we now have ongoing worldwide research programs and sites in the U.S.,

U.K. and Canada. Today, Vertex has more than 1,900 employees around the world, and *Science* magazine named Vertex number one on its 2011 list of Top Employers in the life sciences.

About Alios BioPharma

Alios BioPharma is a biotechnology company located in South San Francisco, California, that is developing novel medicines aimed at the treatment of viral diseases. Alios has an innovative team of highly experienced scientists and clinical researchers who are developing direct acting antiviral agents against several human viral pathogens of public health importance including, hepatotropic and respiratory viruses and other chronic, acute and emerging viral diseases. The overall goal for the Alios therapeutic platform is to maximize patient benefits in areas of high unmet medical need through optimization of potency, safety and tolerability. Alios is the recipient of the 2011 BayBio Pantheon Outstanding Partnering Award.

Special Note Regarding Forward-Looking Statements:

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, including Dr. Mueller's statements in the second paragraph of this press release and statements regarding (i) the expectation that Vertex will receive data from two Phase 1 studies in the second quarter of 2012 that could enable initiation of interferon-free, nucleotide-based combination studies in the second half of 2012; (ii) the design, goals, objectives and expected timing of receiving data from the Phase 1 studies; (iii) the possible combination regimens that could be evaluated in Phase 2 studies and the potential design of such studies; and (iv) the potential for developing ALS-2200 and ALS-2158 together as a dual nucleotide regimen and as part of other combination therapy regimens. While the Company believes the forward-looking statements contained in this press release are accurate, there are a number of factors that could cause actual events or results to differ materially from those indicated by such forward-looking statements. Those risks and uncertainties include, among other things, the possibilities that the outcomes from the Phase 1 studies may not be favorable, that the Company may not be able to successfully develop ALS-2200 or ALS-2158, and the other risks listed under Risk Factors in Vertex's annual report and quarterly reports filed with the Securities and Exchange Commission and available through the Company's website at www.vrtx.com. The Company disclaims any obligation to update the information contained in this press release as new information becomes available.

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