



October 1, 2012

## **Vertex Announces Presentation of New Data from Hepatitis C Development Program at AASLD Annual Meeting**

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today announced that 11 abstracts from its hepatitis C research and development program will be presented at The Liver Meeting<sup>®</sup>, the 63rd Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in Boston, November 9 to 13, 2012.

Presentations will include data on INCIVEK<sup>®</sup> (telaprevir) tablets, Vertex's approved medicine for the treatment of genotype 1 chronic hepatitis C, and two of the company's hepatitis C treatments in development: VX-222, a non-nucleoside polymerase inhibitor, and ALS-2200 (VX-135), a uridine nucleotide analogue pro-drug.

These accepted abstracts are now available on the AASLD website at: <https://www.aasld.org/lm2012>.

### **ALS-2200 (VX-135) Presentations**

1. "ALS-2200, a Novel Once-Daily Nucleotide HCV Polymerase Inhibitor, Demonstrates Potent Antiviral Activity over 7 Days in Treatment-Naïve Genotype 1 (GT1) Patients." November 11, 2012, 5:00 p.m. EST. Oral Presentation #86
2. "Preclinical Characterization of ALS-2200, a Potent Nucleotide Polymerase Inhibitor for the Treatment of Chronic Hepatitis C." November 13, 2012, 8:00 a.m. - 12:00 p.m. EST. Poster Presentation #1882
3. "Analysis of ALS-2200, a Novel Potent Nucleotide Analog, Combination Drug Interactions in the Hepatitis C Virus (HCV) Subgenomic Replicon System." November 13, 2012, 8:00 a.m. - 12:00 p.m. EST. Poster Presentation #1887

### **INCIVEK (telaprevir) Presentations**

1. "Telaprevir in Combination with Peginterferon Alfa-2a/Ribavirin in HCV/HIV Co-infected Patients: SVR24 Final Study Results." November 11, 2012, 4:15 p.m. EST. Oral Presentation #54
2. "Evaluation of Liver and Plasma HCV RNA Kinetics and Telaprevir Levels in Genotype 1 HCV Patients Treated with Telaprevir using Serial Fine Needle Aspirates." November 13, 2012, 9:00 a.m. EST. Oral Presentation #215
3. "The Safety of Telaprevir in the Absence of Interferon and/or Ribavirin: Analysis of On-Treatment Data from the ZENITH Trial." November 11, 2012, 8:00 a.m. - 5:30 p.m. EST. Poster Presentation #786
4. "Factors Predictive of Anemia Development in Treatment-Experienced Patients Receiving Telaprevir (TVR) Plus Peginterferon/Ribavirin (PR) in the REALIZE Trial." November 11, 2012, 8:00 a.m. - 5:30 p.m. EST. Poster Presentation #771
5. "Rate of Disappearance of Telaprevir Resistant Variants Using Clonal and Population Sequence Data from Phase 3 Studies." November 11, 2012, 8:00 a.m. - 5:30 p.m. EST. Poster Presentation #756
6. "Deep Sequencing of the HCV NS3/4A Region Confirms Low Prevalence of the Telaprevir-Resistant Variants Both at Baseline and End of Study." November 11, 2012, 8:00 a.m. - 5:30 p.m. EST. Poster Presentation #1091

### **VX-222 Presentations**

1. "VX-222, Telaprevir and Ribavirin in Treatment-Naïve Patients with Genotype 1 Chronic Hepatitis C: Results of the ZENITH Study Interferon-Free Regimen." November 13, 2012, 11:15 a.m. EST. Oral Presentation #231
2. "Effect of Hepatic Impairment on the Pharmacokinetics of VX-222: Results From a Multicenter Phase 1 Study." November 13, 2012, 8:00 a.m. - 12:00 p.m. EST. Poster Presentation #1880

### **About ALS-2200 (VX-135) and VX-222**

ALS-2200 (VX-135) is a uridine nucleotide analogue pro-drug that appears to have a high barrier to drug resistance based on *in vitro* studies. It is designed to inhibit the replication of the hepatitis C virus by acting on the NS5B polymerase. *In vitro* studies of the compound 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 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.

VX-222 is an oral medicine in development that is a non-nucleoside inhibitor of the HCV NS5B polymerase. Vertex has worldwide commercial rights for VX-222.

## **About INCIVEK**

INCIVEK<sup>®</sup> (telaprevir) tablets is an oral medicine that acts directly on the hepatitis C virus protease, an enzyme essential for viral replication.

INCIVEK was approved by the U.S. Food and Drug Administration (FDA) in May 2011 and by Health Canada in August 2011 for use in combination with pegylated-interferon and ribavirin for adults with genotype 1 chronic hepatitis C with compensated liver disease (some level of damage to the liver but the liver still functions), including cirrhosis (scarring of the liver). INCIVEK is approved for people who are new to treatment, and for people who were treated previously with interferon-based treatment but who did not achieve a sustained viral response, or viral cure (relapsers, partial responders and null responders).

Vertex developed telaprevir in collaboration with Janssen and Mitsubishi Tanabe Pharma. Vertex has rights to commercialize telaprevir in North America where it is being marketed under the brand name INCIVEK (in-SEE-veck). Janssen has rights to commercialize telaprevir in Europe, South America, Australia, the Middle East and certain other countries. In September 2011, telaprevir was approved in the European Union and Switzerland. Telaprevir is known as INCIVO<sup>®</sup> in Europe. Mitsubishi Tanabe Pharma has rights to commercialize telaprevir in Japan and certain Far East countries. In September 2011, telaprevir was approved in Japan and is known as Telavic<sup>®</sup>.

## **IMPORTANT SAFETY INFORMATION**

### **Indication**

INCIVEK<sup>®</sup> (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](http://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.<sup>1</sup> Chronic hepatitis C can lead to serious and life-threatening liver problems, including liver damage, cirrhosis, liver failure or liver cancer.<sup>1</sup> Though many people with hepatitis C may not experience symptoms, others may have symptoms such as fatigue, fever, jaundice and abdominal pain.<sup>1</sup>

Unlike HIV and hepatitis B virus, chronic hepatitis C can be cured.<sup>2</sup> However, approximately 60 percent of people do not achieve SVR,<sup>3,4,5</sup> or viral cure,<sup>6</sup> 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.<sup>7,8</sup>

More than 170 million people worldwide are chronically infected with hepatitis C.<sup>6</sup> In the United States, up to 5 million people have chronic hepatitis C and 75 percent of them are unaware of their infection.<sup>9,10</sup> Hepatitis C is four times more prevalent in the United States compared to HIV.<sup>10</sup> The majority of people with hepatitis C in the United States were born between 1945 and 1965, accounting 82 percent of people with the disease.<sup>11</sup> Hepatitis C is the leading cause of liver transplantations in the United States and is reported to contribute to 15,000 deaths annually.<sup>12,13</sup> 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.<sup>10</sup>

## 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 and other life-threatening diseases.

Founded more than 20 years ago in Cambridge, Mass., we now have ongoing worldwide research programs and sites in the U.S., U.K. and Canada. Today, Vertex has more than 2,000 employees around the world, and for three years in a row, *Science* magazine has named Vertex one of its Top Employers in the life sciences

Vertex's press releases are available at [www.vrtx.com](http://www.vrtx.com).

(VRTX-GEN)

## References:

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<sup>13</sup> S.D. Holmberg, K.N. Ly., et.al. The Growing Burden of Mortality Associated with Viral Hepatitis in the United States, 1999-2007. AASLD 2011 Annual Meeting.

Vertex Pharmaceuticals Incorporated

Media:

Erin Emlock or Zach Barber, 617-444-6992

[mediainfo@vrtx.com](mailto:mediainfo@vrtx.com)

or

Investors:

Kelly Lewis, 617-444-7530

or

Michael Partridge, 617-444-6108

Source: Vertex Pharmaceuticals Incorporated

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