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Health Canada Approves INCIVEK™ (telaprevir) for People With Hepatitis C

- Nearly 4 out of 5 people treated for the first time cleared the virus with INCIVEK combination treatment -

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today announced that Health Canada has approved INCIVEK™ (telaprevir) tablets for a broad group of people 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 (in-SEE-veck) is approved for use in combination with pegylated-interferon and ribavirin, two other medicines approved to treat hepatitis C, and is indicated for people who are new to treatment, and for people who were treated previously but who did not achieve a sustained viral response (SVR, or viral cure). INCIVEK is approved for use in all three major groups of people who did not achieve a viral cure despite prior treatment including: relapsers, partial responders and null responders.

"Early diagnosis and the effective treatment of hepatitis C are critical to the prevention of long-term consequences of the disease, which may include end-stage cirrhosis, liver cancer and the need for a transplant," said Eric Yoshida, M.D., Professor of Medicine and Head, Division of Gastroenterology at the University of British Columbia and an INCIVEK investigator. "INCIVEK is an important new treatment option because it has been shown to help clear the virus for nearly four out of five patients new to treatment."

"Health Canada's rapid approval of INCIVEK underscores the urgent need for new medicines to treat hepatitis C, which affects about a quarter of a million Canadians," said Robert Kauffman, M.D., Ph.D., Senior Vice President and Chief Medical Officer for Vertex. "Until recently, approximately 40 percent of people who underwent a year of treatment for hepatitis C were cured. INCIVEK's ability to nearly double that rate of cure and cut treatment time in half for the majority of patients being treated for the first time marks a turning point in the fight against this disease."

INCIVEK is given as two 375-mg tablets, three times daily. It is given for 12 weeks in combination with pegylated-interferon and ribavirin. After the first 12 weeks, all patients stop receiving INCIVEK and continue treatment with pegylated-interferon and ribavirin alone for an additional 12 weeks or 36 weeks of treatment. With INCIVEK combination treatment, more than 60 percent of people treated for the first time, as well as those who relapsed after previous therapy, are expected to complete all treatment in 24 weeks — half the time needed if they were to take pegylated-interferon and ribavirin alone. All other patients will receive a total of 48 weeks of treatment. Rash and anemia are the most serious side effects associated with INCIVEK. The most common side effects reported with INCIVEK combination treatment include fatigue, itching, nausea, diarrhea, vomiting, anal or rectal problems, and taste changes.

The approval of INCIVEK was based on data from three Phase 3 studies of more than 2,500 people with hepatitis C, which showed that people who received INCIVEK combination treatment achieved significantly higher rates of viral cure (sustained viral response, or SVR) compared to those who received pegylated-interferon and ribavirin alone, regardless of their prior treatment experience:

People new to treatment:	79 percent vs. 46 percent
People who were treated previously but did not achieve a viral cure:	
-- Relapsers:	86 percent vs. 22 percent
-- Partial responders:	59 percent vs. 15 percent
-- Null responders:	32 percent vs. 5 percent

Data from the Phase 3 REALIZE and ADVANCE studies were published on June 23, 2011 in the *New England Journal of Medicine.*

"As the world's first organization dedicated to providing support for research and education into the causes, diagnoses, prevention and treatment of all liver disease, we are all too familiar with the devastating consequences of hepatitis C," said Morris Sherman, Ph.D., FRCPC, M.B., Chairman of the Canadian Liver Foundation (CLF) and an INCIVEK investigator. "We applaud the approval of new medicines like INCIVEK that can significantly improve the treatment of hepatitis C and hope that all

Canadians who need treatment will have access to these medical advances."

Indication

INCIVEK™ (telaprevir) is a prescription medicine that treats a disease in adults called chronic hepatitis C (chronic means lasting a long time). INCIVEK does not work by itself. It is always used in combination with peginterferon alfa and ribavirin.

Important Safety Information

INCIVEK must always be used in combination with peginterferon alfa and ribavirin to treat chronic hepatitis C. A female patient should not take INCIVEK combination treatment if she is or plans to become pregnant, and until six months after treatment ends. A male patient should not take INCIVEK combination treatment if he has a sexual partner who is pregnant or may become pregnant any time during treatment, and until six months after treatment ends.

INCIVEK combination treatment may cause a rash that can become severe. It may also cause a serious skin reaction, a rare side effect. Patients will have their blood checked for anemia and other possible blood problems. Drugs that cause an effect on the electrical conduction of the heart known as QTc prolongation should be taken with caution in patients taking INCIVEK.

Certain medicines can cause serious or life threatening reactions with INCIVEK. Patients should tell their health care provider about all the medicines they take, including over-the-counter medicines, vitamins and herbal medicines.

The most common side effects of INCIVEK include rash, itching, anal or rectal problems, anemia, nausea, diarrhea, vomiting, and taste alteration. This is not a complete list of side effects. Patients should tell their health professional about any unexpected effects or any side effect that bothers them or does not go away.

For more information or questions about INCIVEK please call 1-877-634-VRTX (8789).

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.[6,9]

Hepatitis C in Canada

Approximately 250,000 people in Canada have chronic hepatitis C and more than a third of them do not know they are infected. [9] Three provinces account for 80 percent of hepatitis C infections in Canada: Ontario (42 percent), British Columbia (22 percent) and Quebec (16 percent).[10] Each year up to 5,000 people are newly infected with hepatitis C in Canada and in 2007 alone, nearly 8,000 people were infected.[12,13] In 2010, the annual cost of hepatitis C due to medical treatment and lost productivity in Canada was estimated to reach $1 billion.[11] By 2022, the number of hepatitis C-related deaths is expected to increase by one-third.[12]

Additional resources for media are available at: http://investors.vrtx.com/press.cfm.

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, 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.

About Vertex in Canada

In 2009, Vertex established a research and development site in Laval, Quebec through the acquisition of Virochem Pharma, Inc. Vertex is expanding its existing research and development infrastructure with the addition of commercial and medical teams to support the anticipated launch of INCIVEK (telaprevir) in Canada.

For more information on Vertex, including career opportunities with Vertex Canada, and to view Vertex's press releases, please visit www.vrtx.com.

(VRTX - GEN)

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