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INCIVEK™ (telaprevir) Now Available in Canada for People with Hepatitis C

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

LAVAL, Quebec--(BUSINESS WIRE)-- Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) announced today that INCIVEK™ (telaprevir) tablets are now available in Canada for 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) was approved by Health Canada in August 2011 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 all three major groups of people (relapsers, partial responders and null responders) who were treated previously but who did not achieve a sustained viral response (SVR, or viral cure).

INCIVEK will be the first medicine marketed by Vertex in Canada. Vertex has established its Canadian headquarters in Laval, Quebec where the company currently employs approximately 40 scientists focused on drug discovery and development activities. The company is also building medical and commercial teams to support the use of INCIVEK in Canada, and with the launch of INCIVEK, Vertex plans to continue the expansion of its Canadian workforce, both in Laval and in field-based positions throughout Canada.

"INCIVEK represents an important turning point in the treatment of hepatitis C, and we are pleased to bring this new medicine to people in Canada," said Amit K. Sachdev, Senior Vice President and General Manager for Vertex Pharmaceuticals (Canada) Incorporated. "Today marks a significant step in our commitment to improving the treatment of hepatitis C in Canada, and we are working diligently to ensure people who need this medicine are able to get treatment as quickly as possible."

The Canadian approval of INCIVEK was based on data from a global Phase 3 clinical trial program that enrolled more than 2,500 people with hepatitis C, including patients in Canada. In these studies, people who received INCIVEK combination treatment achieved significantly higher rates of viral cure compared to those who received pegylated-interferon and ribavirin alone, regardless of their prior treatment experience. With INCIVEK combination therapy, more than 60 percent of people new to treatment and those who relapsed after previous therapy are expected to be eligible to complete all treatment in 24 weeks. All other patients receive a total of 48 weeks of treatment. Phase 3 trials showed the following rates of viral cure with INCIVEK combination treatment compared to pegylated-interferon and ribavirin alone:

People new to treatment: 79 percent vs. 46 percent

People who did not achieve a viral cure with previous treatment:

-- Relapsers: 86 percent vs. 22 percent
-- Partial responders: 59 percent vs. 15 percent
-- Null responders: 32 percent vs. 5 percent

In addition, people who had severe liver disease also achieved significantly higher rates of viral cure with INCIVEK combination treatment compared to treatment with pegylated-interferon and ribavirin alone: 62 percent versus 33 percent for those new to treatment with advanced fibrosis or cirrhosis (F3/F4 Metavir) and 87 percent versus 13 percent for people with cirrhosis (F4 Metavir) who relapsed after prior therapy. The Canadian Product Monograph also includes Phase 3 clinical data that showed 68 percent of people new to treatment achieved a rapid virologic response (RVR; had no detectable virus after 4 weeks of treatment) with INCIVEK combination therapy, versus 9 percent for those who received pegylated-interferon and ribavirin alone. RVR is a strong predictor of a person's likelihood of achieving a viral cure.¹

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 Canadian availability of INCIVEK is an important milestone in the fight against hepatitis C, with many people now expected to be able to complete treatment in half the time previously needed with pegylated-interferon and ribavirin alone," said Robert

Myers, MD, Associate Professor and Director of the Viral Hepatitis Clinic at the University of Calgary and an INCIVEK investigator. "This is an encouraging advancement for people with hepatitis C, and we hope that Canadians who need treatment will have access to this important new medication."

Vertex has initiated the process to make INCIVEK accessible to people in Canada through private health insurers and through the provincial and federal drug plans in Canada. The company will implement a comprehensive patient support program to provide financial assistance for costs associated with INCIVEK for people who meet certain program criteria and to provide other support services related to treatment with INCIVEK. Additionally, patients will have access to nurses through a 24-7 hotline where they can receive support, guidance and educational materials about hepatitis C and its treatment. Vertex will also provide nurses and doctors with educational tools and resources so they can offer support and care to their patients with hepatitis C before, during and after the treatment process.

About INCIVEK

INCIVEK is an oral medicine that acts directly on the hepatitis C virus protease, an enzyme essential for viral replication. INCIVEK was approved by Health Canada in August 2011 (Drug Identification Number/DIN: 02371553) and by the U.S. Food and Drug Administration (FDA) in May 2011 for 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 is approved for people who are new to treatment and for people who were treated previously but who did not achieve a sustained viral response or viral cure (relapsers, partial responders and null responders).

INCIVEK (750 mg) is given as two 375 mg tablets three times daily for 12 weeks in combination with pegylated-interferon and ribavirin. Each monthly package of INCIVEK contains four weekly boxes that include daily blister strips. 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.

Vertex developed telaprevir in collaboration with Tibotec BVBA 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). Through its affiliate, Janssen, Tibotec 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[®] 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 will be known as Telavic[®].

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 the full Canadian Product Monograph or for more information or questions about INCIVEK, please call 1-877-574-4298 or visit www.vrtx.ca.

About Hepatitis C

Hepatitis C is a serious liver disease caused by the hepatitis C virus (HCV), which is spread through direct contact with the

blood of infected people and ultimately affects the liver.² Chronic hepatitis C can lead to serious and life-threatening liver problems, including liver damage, cirrhosis, liver failure or liver cancer.² Though many people with hepatitis C may not experience symptoms, others may have symptoms such as fatigue, fever, jaundice and abdominal pain.²

Unlike HIV and hepatitis B virus, chronic hepatitis C can be cured.³ However, approximately 60 percent of people do not achieve SVR,^{4,5,6} or viral cure⁷, 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.^{8,9}

More than 170 million people worldwide are chronically infected with hepatitis C.^{10,11}

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.¹¹ Three provinces account for 80 percent of hepatitis C infections in Canada: Ontario (42 percent), British Columbia (22 percent) and Quebec (16 percent).¹² 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.¹² By 2022, the number of hepatitis C-related deaths is expected to increase by one-third.¹³

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, 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.

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 launch of INCIVEK (telaprevir) in Canada. Vertex is currently hiring for a variety of positions in Canada to support its research, medical and commercial teams.

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

Special Note Regarding Forward-Looking Statements

This press release contains forward-looking statements, as defined in the Private Securities Litigation Reform Act of 1995, as amended, including statements regarding (i) Vertex's plans to continue the expansion of its Canadian workforce; (ii) Vertex working diligently to ensure Canadians who need INCIVEK are able to get treatment as quickly as possible; (iii) the expectation that many people will be able to complete treatment in half the time previously needed with pegylated-interferon and ribavirin alone; (iv) the hope that Canadians who need treatment will have access to this important new medication and (v) the process required to make INCIVEK accessible through private health insurers and provincial and federal drug plans in Canada. 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, risks related to the commercialization of INCIVEK in Canada 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 Vertex's website at www.vrtx.com. Vertex disclaims any obligation to update the information contained in this press release as new information becomes available.

¹ Fried MW et al. J Hepatology. 2011 Jul;55(1):69-75.

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- ³ Pearlman BL and Traub N. Sustained Virologic Response to Antiviral Therapy for Chronic Hepatitis C Virus Infection: A Cure and So Much More. *Clin Infect Dis*. 2011 Apr;52(7):889-900.
- ⁴ Manns MP, McHutchison JG, Gordon SC, et al. Peginterferon alfa-2b plus ribavirin compared with interferon alfa-2b plus ribavirin for initial treatment of chronic hepatitis C: a randomised trial. *Lancet*. 2001;358:958-965.
- ⁵ Fried MW, Shiffman ML, Reddy KR, et al. Peginterferon alfa-2a plus ribavirin for chronic hepatitis C virus infection. *N Engl J Med*. 2002;347:975-982.
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- ⁷ Ghany MG, Strader DB, Thomas DL, Seeff, LB. Diagnosis, management and treatment of hepatitis C; An update. *Hepatology*. 2009;49 (4):1-40.
- ⁸ Morgan TR, Ghany MG, Kim HY, Snow KK, Lindsay K, Lok AS. Outcome of sustained virological responders and non-responders in the Hepatitis C Antiviral Long-Term Treatment Against Cirrhosis (HALT-C) trial. *Hepatology*. 2008;50(Suppl 4):357A (Abstract 115).
- ⁹ Veldt BJ, Heathcote J, Wedmeyer H. Sustained virologic response and clinical outcomes in patients with chronic hepatitis C and advanced fibrosis. *Annals of Internal Medicine*. 2007; 147: 677-684.
- ¹⁰ Ghany MG, Strader DB, Thomas DL, Seeff, LB. Diagnosis, management and treatment of hepatitis C; An update. *Hepatology*. 2009;49 (4):1-40.
- ¹¹ Public Health Agency of Canada. Hepatitis C: Get the facts. You could have it and not know it. <http://www.phac-aspc.gc.ca/hepc/pubs/getfacts-informezvous/index-eng.php>. Updated September 21, 2010. Accessed August 15, 2011.
- ¹² Public Health Agency of Canada. Modeling the incidence of prevalence of hepatitis C infection and its sequelae in Canada, 2007. <http://www.phac-aspc.gc.ca/sti-its-surv-epi/model/results-eng.php>. Updated October 20, 2010. Accessed August 15, 2011.
- ¹³ Sherman M, Sharfran S, Burak K, et al. Management of chronic hepatitis C consensus guidelines. *Can J Gastroenterol*. 2007;21 (Suppl C):25C-34C.

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