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INCIVEK™ (telaprevir) Now Funded in Alberta and New Brunswick for People with Hepatitis C

- Majority of provinces now fund INCIVEK -

LAVAL, Quebec--(BUSINESS WIRE)--Vertex Pharmaceuticals Incorporated announced today that the provinces of Alberta and New Brunswick are now funding INCIVEK™ (telaprevir) tablets in combination with pegylated interferon and ribavirin for residents with genotype 1 chronic hepatitis C. The Alberta Health decision comes following an evaluation by the Alberta Provincial Drugs and Therapeutic Committee.

"Direct-acting antiviral agents are an important advancement in the treatment of hepatitis C, but to make a significant impact they need to be accessible to all patients, regardless of where they live, their financial status or disease severity"

INCIVEK funding in Alberta and New Brunswick includes patients who are being treated for the first time, as well as those who were treated previously, but did not achieve a sustained virologic response (SVR, or virologic cure), including null responders. Null responders, or those who do not respond to initial treatment, typically have the most difficult time achieving a cure.

"In clinical studies, INCIVEK combination therapy showed the ability to cure nearly four out of five people infected with genotype-1 hepatitis C who were being treated for the disease for the first time and many were eligible to complete all treatment in 24 weeks, marking a fundamental shift from how the disease was previously treated," said Robert Myers, MD, FRCP©, Associate Professor and Director of the Viral Hepatitis Clinic at the University of Calgary and an INCIVEK investigator.

INCIVEK is now funded in seven provinces and territories, including Alberta, British Columbia, Saskatchewan, Quebec, New Brunswick, Nova Scotia and the Yukon. INCIVEK is also currently accessible to Canadians through most private health insurers. At the federal level, the Non-Insured Health Benefits (NIHB) for First Nations and Inuit has listed INCIVEK. Vertex continues to work with remaining provincial governments to make INCIVEK accessible to people with hepatitis C, including those in Ontario, where the greatest number of people with the virus reside. The hepatitis C virus is the highest-ranked infectious disease in terms of disease burden in Ontario, including years of life lost due to premature mortality.[1]

"Direct-acting antiviral agents are an important advancement in the treatment of hepatitis C, but to make a significant impact they need to be accessible to all patients, regardless of where they live, their financial status or disease severity," said Morris Sherman, MB BCH, PhD, FRCP©, and Chairman of the Canadian Liver Foundation (CLF). "The CLF commends Alberta and New Brunswick for recognizing the needs of people with hepatitis C and providing access to this effective treatment option. We urge all remaining provinces to fund all new hepatitis C treatment options as quickly as possible."

About INCIVEK

INCIVEK™ (telaprevir) is a prescription medicine for the treatment of adults with chronic hepatitis genotype 1 hepatitis C who have either not received previous treatment or who failed prior treatment with peginterferon alfa or peginterferon alfa and ribavirin. INCIVEK must not be taken by itself, and is always used in combination with peginterferon alfa and ribavirin.

Health Canada approved INCIVEK in August 2011. In February 2012, Vertex received a positive recommendation with criteria to list INCIVEK for reimbursement through Priority Review granted by the Common Drug Review (CDR). 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. Phase 3 trials showed higher rates of viral cure (sustained viral response, or SVR, 24 weeks after the end of all treatment) with INCIVEK combination treatment compared to pegylated-interferon and ribavirin alone:

People new to treatment:

79 per cent (285/363) vs. 46 per cent (166/631)

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

Relapsers: 86 per cent (246/286) vs. 22 per cent (15/68)

Partial responders: 59 per cent (57/97) vs. 15 per cent (4/27)

Null responders: 32 per cent (47/147) vs. 5 per cent (2/37)

Vertex has implemented a comprehensive patient support program called INCIVEK Care™ that is designed to coordinate reimbursement, provide financial assistance for costs associated with INCIVEK for people who meet certain program criteria and offer other support services related to treatment with INCIVEK.

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® 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®.

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 healthcare 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. 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, 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.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.[3] However, approximately 60 per cent of people do not achieve SVR,[4,5,6] or viral cure,[7] 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.[6,9]

Hepatitis C in Alberta and New Brunswick

Approximately 250,000 people in Canada have chronic hepatitis C and more than a third of them do not know they are infected. [10] In 2009, 11,357 cases of hepatitis C were reported in Canada, and of that, 1,129 cases were reported in Alberta, and 196 cases in New Brunswick.[9,11,12] Males with hepatitis C living in Alberta outnumber females with hepatitis C living in Alberta with a ratio of two to one.[10] In Alberta, Hepatitis C rates are higher in the aboriginal population.[10] In 2011, newly reported cases of hepatitis C decreased across all age groups in New Brunswick, except among individuals aged 25-29 where the rate of hepatitis C increased.[13]

In 2010, the annual cost of hepatitis C due to medical treatment and lost productivity in Canada was estimated to reach $1 billion.[14] By 2022, the number of hepatitis C-related deaths is expected to increase by one-third.[15]

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.

About Vertex in Canada

In 2009, Vertex established a research and development site in Laval, Quebec through the acquisition of Virochem Pharma, Inc. Vertex employs approximately 50 researchers and support staff in Laval and has also established Commercial and Medical teams in Canada. For more information on Vertex, including career opportunities with Vertex Canada, and to view Vertex's press releases, please visit the company's corporate website at www.vrtx.com.

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