

April 24, 2012

INCIVEK™ (telaprevir) Now Funded for People With Hepatitis C in Quebec and Saskatchewan

- Vertex working with other provincial funding agencies to make INCIVEK available to more people in Canada -

LAVAL, Quebec--(BUSINESS WIRE)-- Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) announced today that the province of Quebec is now funding INCIVEK[™] (telaprevir) tablets for residents living with chronic hepatitis C. The decision comes following a priority evaluation by the Institut National D'Excellence en Santé et en Services Sociaux (INESSS). This decision includes funding for 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, have the hardest time achieving a cure. INCIVEK is the only direct-acting antiviral medicine approved for the treatment of this group of patients. Funding in Quebec will be provided for patients with all levels of fibrosis (scarring of the liver) and in combination with available pegylated-interferon and ribavirin combinations. Earlier this month, Saskatchewan became the first province in Canada to fund this new medicine. Vertex is working closely with other provincial reimbursement agencies to secure funding that will make INCIVEK accessible to more people with hepatitis C across all of Canada.

"In clinical studies, INCIVEK demonstrated the ability to cure nearly four out of five people infected by the hepatitis C genotype-1 virus who had not been previously treated for hepatitis C and to cut treatment time to 24 weeks for most patients, which marks a fundamental shift in treatment," said Dr. Marc Bilodeau from the Liver Unit of the Centre hospitalier de l'Université de Montréal. "The decision by the Minister of Health and Social Services of Quebec to reimburse INCIVEK underscores the urgent need for new medicines to treat this potentially life-threatening but curable disease, which affects about a quarter of a million people in Canada."

Health Canada approved INCIVEK for use in combination with pegylated-interferon and ribavirin in August 2011 for adults with genotype 1 chronic hepatitis C who have not received previous treatment or who failed a prior course of treatment with an interferon-based regimen. Vertex received a positive recommendation and criteria to list INCIVEK for reimbursement in February 2012 through Priority Review granted by the Common Drug Review (CDR). The approval was based on data from Phase 3 studies that showed significant improvements in rates of virologic cure among people with hepatitis C who were treated with INCIVEK combination therapy compared to pegylated-interferon and ribavirin alone, regardless of their prior treatment experience:

People new to treatment: 79 per cent vs. 46 per cent

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

Relapsers: 86 per cent vs. 22 per cent

Partial responders: 59 per cent vs. 15 per cent

Null responders: 32 per cent vs. 5 per cent

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.

"Direct-acting antivirals represent a major step forward in the treatment of hepatitis C," said Dr. Morris Sherman, Chairman of the Canadian Liver Foundation. "In order for this new class of medicines to make a significant impact however, they need to be accessible to all patients regardless of where they live, financial status or severity of their disease. The CLF has argued that to effectively treat hepatitis C, the medical community must have access to the most effective therapies in order to best meet the needs of their patients. We applaud Saskatchewan and Quebec for prioritizing the needs of hepatitis C patients and providing access to this new treatment option."

Eligibility criteria for treatment with INCIVEK in Quebec can be viewed online at: https://www.prod.ramq.gouv.qc.ca/DPI/PO/Commun/PDF/Liste Med/Liste Med/Liste med 2012 04 20 en.pdf

Eligibility criteria for treatment with INCIVEK in Saskatchewan under the Exception Drug Status program are available at: <a href="http://formulary.drugplan.health.gov.sk.ca/FormularyBulletins/Bul

In addition, INCIVEK is currently accessible to Canadians through most private health insurers. Vertex has implemented a comprehensive patient support program called INCIVEK Care™ that is designed to coordinate reimbursement, provide financi assistance for costs associated with INCIVEK for people who meet certain program criteria and provide other support services related to treatment with INCIVEK.

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

Unlike HIV and hepatitis B virus, chronic hepatitis C can be cured.² However, approximately 60 per cent 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 Quebec accounts for 16 per cent of hepatitis C infections in Canada, and 32,000 cases have been reported in Quebec since 1991. ^{10,11} In 2009, 11,357 cases of hepatitis C were reported in Canada, and of that, 1,793 cases were reported in Quebec. ^{9,11} 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

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 2,000 employees around the world, and *Science* magazine named Vertex number one on its 2011 list of 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. 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.

(VRTX - GEN)

References:

¹ Canadian Liver Foundation. Viral Hepatitis: What You Need to Know. Available at: http://www.liver.ca/hepatitis/hepatitis-c.aspx. Accessed April 20, 2012.

- ² 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.
- ³ 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.
- ⁴ 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.
- ⁵ McHutchison JG, Lawitz EJ, Shiffman ML, et al; IDEAL Study Team. Peginterferon alfa-2b or alfa-2a with ribavirin for treatment of hepatitis C infection. *N Engl J Med*. 2009;361:580-593.
- ⁶ Ghany MG, Strader DB, Thomas DL, Seeff, LB. Diagnosis, management and treatment of hepatitis C; An update. *Hepatology*. 2009;49 (4):1-40.
- ⁷ 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).
- ⁸ 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.
- ⁹ 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 March 21, 2012.
- ¹⁰ 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 March 21, 2012.
- ¹¹ Sante et Services sociaux Quebec. Hepatitis C Virus. http://itss.gouv.qc.ca/?lg=en#/itss/hepatite_c. Accessed March 21, 2012.
- ¹² Public Health Agency of Canada. A renewed public health response to address hepatitis C: A summary report of the priority-setting process and strategic framework to action. http://dsp-psd.pwgsc.gc.ca/collection_2010/aspc-phac/HP40-44-2009-eng.pdf. Updated June 2009. Accessed March 21, 2012.
- 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.

Vertex Pharmaceuticals Incorporated

Media:

Zach Barber Erin Emlock Dawn Kalmar 617-444-6992

mediainfo@vrtx.com

or

For French-speaking press, please contact: Morin Relations Publiques Steven Ross, 514-289-8688, poste 236 steven@morinrp.com

or

Investors:

Michael Partridge, 617-444-6108

Source: Vertex Pharmaceuticals Incorporated

News Provided by Acquire Media