



## PRESS RELEASE

### **British Columbia Joins Other Provinces to Reimburse AbbVie's HOLKIRA™ PAK**

- *HOLKIRA PAK now reimbursed in British Columbia for patients with genotype 1 hepatitis C virus infection*
- *Saskatchewan, Manitoba and Yukon also list HOLKIRA PAK*
- *In Phase 3 clinical trials, HOLKIRA PAK (with or without ribavirin) cured an overall 97 percent of genotype 1 HCV patients; additionally, 98 percent of patients completed treatment*

**MONTREAL, CANADA, AUGUST 4, 2015** – AbbVie's HOLKIRA PAK (ombitasvir/paritaprevir/ritonavir film-coated tablets; dasabuvir film-coated tablets) will now be reimbursed in British Columbia, Saskatchewan, Manitoba and Yukon. HOLKIRA PAK is an all-oral, short-course (12 weeks for the majority of patients), interferon-free treatment, with or without ribavirin (RBV), for the treatment of patients with genotype 1 (GT1) chronic hepatitis C virus (HCV) infection, including those with compensated cirrhosis.

An estimated 242,500 Canadians are living with hepatitis C, according to the Public Health Agency of Canada.<sup>1</sup> A significant number of the estimated cases in Canada remain undiagnosed, although the exact proportion is unclear.<sup>2</sup> There are six different genotypes of hepatitis C; two-thirds of Canadians living with hepatitis C have GT1 – either subtype 1a or 1b – which are the most difficult to cure.<sup>3</sup>

“We have the potential today to screen, and now to cure hepatitis C in a large percentage of those patients treated. With these newer treatments, which have high cure rates and a very low side-effect profile, we can potentially eliminate hepatitis C in Canada,” said Dr. Alnoor Ramji, clinical associate professor of medicine, Gastroenterology and Hepatology, Division of Gastroenterology, University Of British Columbia. “The British Columbia government, as well as all the other provincial governments, should be congratulated for providing these treatments to people living with hepatitis C. It is a step in the right direction since hepatitis C has devastating consequences when left untreated.”

The decision by the various provinces and territory to reimburse HOLKIRA PAK stems from the June 20<sup>th</sup> Common Drug Review (CDR) positive recommendation<sup>4</sup> under the following minimal conditions: liver fibrosis stage of  $\geq 2$ , and treatment should be initiated by physicians with experience in the management of hepatitis C.

In British Columbia, HOLKIRA PAK can be prescribed for treatment-naïve and treatment-experienced adult patients with chronic hepatitis C genotype 1 infection, with compensated liver disease, (including compensated cirrhosis) according to specific criteria<sup>5</sup>. The listing became effective on World Hepatitis Day, on Tuesday, July 28<sup>6</sup>.

“The addition of new, highly curative treatments for hepatitis C is welcomed greatly by the community affected by this life-threatening illness,” said Daryl Luster, president, Pacific Hepatitis C Network. “As a



person who is in daily contact with people living with hepatitis C, I hear their excitement about new, more effective therapies. I myself lived with hepatitis C, and I support the addition of these treatments to the Pharmacare Plan.”

In Saskatchewan, HOLKIRA PAK is an Exception Status benefit, effective August 1, for treatment-naïve and treatment-experienced adult patients with chronic hepatitis C genotype 1 infection, with compensated liver disease, (including compensated cirrhosis) according to criteria<sup>7</sup>.

In Manitoba, HOLKIRA PAK was added as a Part 3 benefit on Manitoba Pharmacare on July 22. The Part 3 listing is as follows: for treatment-naïve and treatment-experienced adult patients with chronic hepatitis C GT1 infection, with compensated liver disease (including compensated cirrhosis)<sup>8</sup>.

In the Yukon, HOLKIRA PAK has been available since June 25 for treatment-naïve and treatment-experienced adult patients with chronic hepatitis C genotype 1 infection, with compensated liver disease (including compensated cirrhosis)<sup>9</sup>.

“AbbVie is committed to addressing the burden of disease for people living with hepatitis C, an increasing Canadian and global health concern,” said Stéphane Lassignardie, general manager, AbbVie Canada. “Since the launch of HOLKIRA PAK, AbbVie vowed to take a thoughtful and collaborative approach with governments, medical and patient organizations to bring HOLKIRA PAK to Canadians living with genotype 1 hepatitis C. Today, we are fulfilling this ambition, with HOLKIRA PAK being listed on several provincial formularies.”

Canadians prescribed HOLKIRA PAK will have the opportunity to be enrolled in AbbVie Care, AbbVie’s signature care program. AbbVie Care provides support to people living with hepatitis C. The program is designed to provide a wide range of customized services including reimbursement and financial support, pharmacy services coordination with pharmacies trained in hepatitis C, lab work reminders and coordination, personalized education and ongoing disease management support throughout the treatment and beyond.

HOLKIRA PAK combines three direct-acting antivirals to attack the virus at three separate stages of its replication process. In Phase 3 clinical trials, HOLKIRA PAK (with or without ribavirin) cured an overall 97 percent of GT1 HCV patients, and 98 percent of patients completed treatment.

HOLKIRA PAK was approved by Health Canada on December 22, 2014. The approval of HOLKIRA PAK was supported by a robust clinical development program that was designed to study the safety and efficacy of the regimen in six pivotal Phase 3 studies with more than 2,300 patients across 25 countries, including one trial exclusively in subjects with cirrhosis.

#### **About HOLKIRA PAK**

HOLKIRA PAK consists of the fixed-dose combination of ombitasvir/paritaprevir/ritonavir, taken once daily, and dasabuvir taken twice daily. HOLKIRA PAK is administered with or without ribavirin, depending on the type of hepatitis C virus in cause, the treatment history of the patient and the presence/absence of cirrhosis. The combination of three different mechanisms of action interrupts the hepatitis C virus



replication process with the goal of optimizing sustained virologic response across different patient populations.

The complete HOLKIRA PAK Product Monograph is available at the following location on Health Canada's website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website [www.abbvie.ca](http://www.abbvie.ca), or by calling 1-888-704-8271.

Additional information about AbbVie's chronic hepatitis C clinical program can be found on [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### **Important Safety Information**<sup>10</sup>

To help avoid possible side effects and ensure proper use, talk to your health care professional before you take HOLKIRA PAK. Talk about any health conditions or problems you may have, including if you:

- are using a medicine containing ethinyl estradiol for contraception or for other reasons. You must not use medicines that contain ethinyl estradiol while taking HOLKIRA PAK. Your doctor will ask you to stop or consider changing to a different type of contraceptive medicine during your treatment.
- have liver problems other than hepatitis C infection.
- have any other medical condition.
- have had a liver transplant.
- are breastfeeding or plan to breastfeed. It is not known if HOLKIRA PAK passes into your breast milk. You and your health care provider should decide if you will take HOLKIRA PAK or breastfeed. You should not do both.
- You or your partner should not become pregnant while taking HOLKIRA PAK with ribavirin and for six months after treatment is over.

Other warnings you should know about:

Let your health care provider know if you develop nausea, vomiting, loss of appetite, yellowing of your skin or eyes, or darkening of your urine while on treatment with HOLKIRA PAK.

If HOLKIRA PAK is administered with ribavirin, the warnings and precautions for ribavirin also apply to this combination regimen. Refer to the ribavirin Patient Medication Information for a full list of the warnings and precautions for ribavirin.

It is not known if taking HOLKIRA PAK is safe and effective in children under 18 years of age.

Your doctor may do blood tests before you start your treatment and regularly during your treatment. These blood tests are done to help your doctor to check if the treatment is working for you.

Tell your health care professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.



HOLKIRA PAK should not be administered with other ritonavir-containing medicines (NORVIR<sup>®</sup>, KALETRA<sup>®</sup>). When co-administered with HOLKIRA PAK, atazanavir or darunavir should be taken without ritonavir.

### **About AbbVie**

AbbVie is a global, research-based biopharmaceutical company formed in 2013 following separation from Abbott Laboratories. The company's mission is to use its expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world's most complex and serious diseases. Together with its wholly-owned subsidiary, Pharmacyclics, AbbVie employs more than 28,000 people worldwide and markets medicines in more than 170 countries. For further information on the company and its people, portfolio and commitments, please visit [www.abbvie.ca](http://www.abbvie.ca) and [www.abbvie.com](http://www.abbvie.com). Follow [@abbvie](https://twitter.com/abbvie) on Twitter or view careers on our [Facebook](#) or [LinkedIn](#) page.

###

<sup>1</sup> Public Health Agency of Canada. Hepatitis C Quick Facts. <http://www.phac-aspc.gc.ca/hepc/index-eng.php>  
Accessed on August 4, 2015

<sup>2</sup> An update on the management of chronic hepatitis C: Consensus guidelines from the Canadian Association for the Study of the Liver, Canadian Journal of Gastroenterology, Vol 26 No 6, June 2012

<sup>3</sup> Hepatitis C Online. <http://www.hepatitisc.uw.edu/go/treatment-infection/treatment-genotype-1/core-concept/all>  
Accessed on August 4, 2015

<sup>4</sup> CADTH. <https://www.cadth.ca/sites/default/files/cdr/complete/cdr-complete-SR0406-Holkira-Pak-June-22-2015-e.pdf>  
Accessed on August 4, 2015

<sup>5</sup> The Government of British Columbia. <http://www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/pharmacare/prescribers/limited-coverage-drug-program/limited-coverage-drugs-ombitasvir-paritaprevir-ritonavir-and-dasabuvir>  
Accessed on August 4, 2015

<sup>6</sup> The Government of British Columbia. <https://news.gov.bc.ca/releases/2015HLTH0053-001186>  
Accessed on August 4, 2015

<sup>7</sup> The Government of Saskatchewan. <http://www.saskatchewan.ca/government/news-and-media/2015/july/28/saskatchewan-supporting-patients-with-hepatitis-with-new-drug>  
Accessed on August 4, 2015

<sup>8</sup> The Government of Manitoba. <http://news.gov.mb.ca/news/index.html?item=35642&posted=2015-07-27>  
Accessed on August 4, 2015



<sup>9</sup> Yukon Drug Formulary.

<http://www.hss.gov.yk.ca/drugformulary.php>

Accessed on August 4, 2015

<sup>10</sup> HOLKIRA PAK (ombitasvir/paritaprevir/ritonavir film-coated tablets; dasabuvir film coated tablets) Product Monograph. Date of Revision: December 22, 2014

[http://www.abbvie.ca/content/dam/abbviecorp/ca/english/docs/HOLKIRA\\_PAK\\_PM\\_EN.pdf](http://www.abbvie.ca/content/dam/abbviecorp/ca/english/docs/HOLKIRA_PAK_PM_EN.pdf)

Accessed on August 4, 2015

**For further information:**

Eileen Murphy

AbbVie Canada

514-832-7788

[eileen.murphy@abbvie.com](mailto:eileen.murphy@abbvie.com)