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PRESS RELEASE

AbbVie Receives Health Canada Approval of HOLKIRA™ PAK for the Treatment of Chronic Genotype 1 Hepatitis C

- *New all-oral, short-course (12 weeks), interferon-free treatment available in Canada for genotype 1 hepatitis C patients*
- *In Phase 3 clinical trials, HOLKIRA PAK (with or without ribavirin) cured an overall 97 percent of GT1 HCV patients; additionally, 98 percent of patients completed treatment*
- *HOLKIRA PAK was evaluated in more than 2,300 patients in over 25 countries, demonstrating consistently high cure rates across a large and diverse patient population*

MONTREAL, CANADA, DECEMBER 23, 2014 – AbbVie receives Health Canada approval for HOLKIRA PAK (ombitasvir/paritaprevir/ritonavir film-coated tablets; dasabuvir film-coated tablets), 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 cirrhosis. The approval of HOLKIRA PAK is 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, including one trial exclusively in subjects with cirrhosis, with more than 2,300 patients across 25 countries.

"Hepatitis C is a devastating disease that causes more years of life lost than any infectious disease in the country. With the introduction of life-saving therapies that offer high cure rates, we can finally prevent complications of the disease and it actually raises the possibility that we even eliminate the disease from Canada altogether," said Dr. Jordan Feld, a hepatologist at the Francis Family Liver Clinic at Toronto Western Hospital, part of the University Health Network. "As physicians, we are thrilled to have an alternative to interferon. In just 12 to 24 weeks of pills with few or no side effects, we are able to cure people who have been living with this disease for decades. This is history in the making."

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

HOLKIRA PAK is the only hepatitis C treatment to combine 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. In Phase 2 and 3 clinical trials, the overall rates of discontinuation due to adverse reactions were low (0.2 percent).

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"When I was first diagnosed with hepatitis C, I was hopeless and afraid because I didn't know what the future held for me, but AbbVie gave me hope," says Stéphanie Léger who was diagnosed with hepatitis C in 2010. "I am grateful to have been given the opportunity to participate in AbbVie's clinical trial. Today, now that I am cured, I can live my life to the fullest."

The recommended treatment regimens and durations for HOLKIRA PAK are[4]:

Patient Population	Treatment	Duration
Genotype 1a, without cirrhosis	HOLKIRA PAK + ribavirin	12 weeks
Genotype 1b, without cirrhosis	HOLKIRA PAK	12 weeks
Genotypes 1a and 1b, with cirrhosis	HOLKIRA PAK + ribavirin	12 weeks*
*24 weeks of HOLKIRA PAK + ribavirin is recommended for patients with genotype 1a-infection with cirrhosis who have had a previous null response to pegylated interferon (pegIFN) and ribavirin. Note: HOLKIRA PAK with ribavirin is recommended in patients with an unknown genotype 1 subtype or with mixed genotype 1 infection.		

"HOLKIRA PAK*'s* approval underlines AbbVie's ongoing commitment to providing solutions for unmet medical needs and to solving some of today's most complex health challenges," said Stéphane Lassignardie, General Manager, AbbVie Canada. "By delivering high cure rates, our all-oral, interferon-free regimen provides adults living with genotype 1 chronic hepatitis C with a breakthrough solution."

Canadians prescribed HOLKIRA PAK will have the opportunity to be enrolled in AbbVie Care, AbbVie's signature care program designed to provide a wide range of services including reimbursement assistance, education and ongoing disease management support. AbbVie Care will support health care professionals and people living with genotype 1 hepatitis C throughout their treatment journey to achieve high cure rates in the real world.

AbbVie's chronic HCV treatment known as VIEKIRA PAK™ in the United States was approved by the Food and Drug Administration (FDA) on December 19. On November 21, the European Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) granted positive opinions for AbbVie's VIEKIRAX + EXVIERA. The European Commission will review the opinions and make a final decision sometime in the first quarter of 2015.

About HOLKIRA PAK

HOLKIRA PAK consists of the fixed-dose combination of paritaprevir/ritonavir (150/100mg) co-formulated with ombitasvir (25mg), dosed once daily, and dasabuvir (250mg) with or without ribavirin (weight-based), dosed twice daily. 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, or by calling 1-888-704-8271.

Additional information about AbbVie's chronic hepatitis C clinical program can be found on www.clinicaltrials.gov.

Important Safety Information
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®, KALETRA®). When co-administered with HOLKIRA PAK, atazanavir or darunavir should be taken without ritonavir.

AbbVie's Hepatitis C Development Program
The AbbVie HCV clinical development program is intended to advance scientific knowledge and clinical care by investigating an interferon-free, all-oral regimen with and without ribavirin with the goal of producing high sustained virologic response rates in as many patients as possible, including those that typically do not respond well to treatment, such as previous non-responders to interferon-based therapy or patients with advanced liver fibrosis or cirrhosis.

AbbVie's chronic HCV treatment combines three direct-acting antivirals, each with a distinct mechanism of action that targets and inhibits specific HCV proteins of the viral replication process.

Paritaprevir was discovered during the ongoing collaboration between AbbVie and Enanta Pharmaceuticals (NASDAQ: ENTA) for HCV protease inhibitors and regimens that include protease inhibitors. Paritaprevir has been developed by AbbVie for use in combination with AbbVie's other investigational medicines for the treatment of hepatitis C.

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. AbbVie employs approximately 25,000 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. Follow @abbvie on Twitter or view careers on our Facebook or LinkedIn page.

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[1]Public Health Agency of Canada. Hepatitis C Quick Facts. http://www.phac-aspc.gc.ca/hepc/index-eng.php. Accessed on November 24, 2014

[2] An update on the management of chronic hepatitis C: Consensus guidelines from the Canadian Association for the Study of the Liver, Canadian Journal of Gastroenteroly, Vol 26 No 6, June 2012

[3]Hepatitis C Online. http://www.hepatitisc.uw.edu/go/treatment-infection/treatment-genotype-1/core-concept/all Accessed on December 12, 2014

[4]HOLKIRA PAK (ombitasvir/paritaprevir/ritonavir film-coated tablets; dasabuvir film coated tablets) Product Monograph. Date of Revision: December 22, 2014

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