

## PRESS RELEASE

### **AbbVie's TECHNIVIE™ Receives Health Canada Approval for Genotype 4 Chronic Hepatitis C Infection**

- *TECHNIVIE provides an opportunity to treat adults who have genotype 4 (GT4) chronic hepatitis C virus (HCV) infection without cirrhosis, a population historically considered difficult-to-treat*
- *TECHNIVIE is the first and only all-oral, interferon-free, direct-acting antiviral treatment approved in Canada for adult patients with GT4 chronic HCV infection*
- *Approval is supported by a Phase II clinical trial of 135 chronic HCV GT4 patients, which demonstrated 100 percent sustained virologic response rates at 12 weeks post-treatment (SVR<sub>12</sub>) in patients who took TECHNIVIE with ribavirin (RBV)*

**MONTREAL, CANADA, NOVEMBER 24, 2015** – AbbVie, a global, biopharmaceutical company, today announced that Health Canada granted a Notice of Compliance (NoC) to TECHNIVIE (ombitasvir/paritaprevir/ritonavir tablets) in combination with ribavirin (RBV) for the treatment of adults with genotype 4 (GT4) chronic hepatitis C virus (HCV) infection without cirrhosis who are either treatment naïve or previously treated with peginterferon and ribavirin.

"Over the last several years, there has been a major focus on hepatitis C genotype 1 disease. The optimal protocol for treating hepatitis C genotype 4 patients was not well defined. As a practicing hepatologist, I am thrilled that finally there is a cure for people living with hepatitis C genotype 4, which is relatively hard to eradicate," explains Dr. Magdy Elkhashab, Gastroenterologist/Hepatologist, Director of the Toronto Liver Centre. "This new therapy, which is given orally, can cure the disease in genotype 4 patients in almost 100% of cases. These are really exciting times. When I started my practice 20 years ago, I saw cure rates of 4 to 6%. I can truly say that I have seen the whole hepatitis C story unfold."

HCV GT4 has historically been difficult to treat. Egypt has the highest prevalence with more than 90% of infections due to genotype 4. Genotype 4 has been spreading in several Western countries, including Canada, due to variations in population structure, immigration, routes of transmission, travel and tourism.<sup>1,2</sup>

"The approval of TECHNIVIE by Health Canada is further proof of AbbVie's ongoing commitment to help address the burden of hepatitis C. We are determined to provide best-in-class solutions for people living with hepatitis C in Canada, especially through our support program AbbVie Care," said Stéphane Lassignardie, general manager, AbbVie Canada.

Virologic cure is defined as a sustained virologic response (SVR), which is when the virus is no longer detectable in the patient's blood 12 weeks after treatment (SVR<sub>12</sub>).<sup>3</sup>



### **About the PEARL-I Study**

This approval of TECHNIVIE is based on data from the PEARL-I study, which demonstrated 100 percent sustained virologic response rates at 12 weeks post-treatment (SVR<sub>12</sub>) in patients who received TECHNIVIE and RBV for 12 weeks. PEARL-I is an open-label Phase 2b study that evaluated the efficacy and safety of TECHNIVIE in GT4 chronic HCV patients without cirrhosis. The study included GT4 patients who were new to therapy (n=42/42) or who had failed previous treatment with pegylated interferon (pegIFN) and RBV (n=49/49). Additionally, 91 percent of patients who were new to therapy achieved SVR<sub>12</sub> (n=40/44) after taking TECHNIVIE without RBV. In the treatment-naïve group without RBV, on-treatment virologic failure was reported in one patient (two percent), and two patients (five percent) experienced post-treatment relapse. There were no virologic failures in the other treatment arms.

There were no discontinuations due to adverse events in these patients. The most commonly reported treatment-emergent adverse events (greater than 10 percent) observed in patients receiving TECHNIVIE with RBV were asthenia, fatigue, and headache.

### **About TECHNIVIE**

TECHNIVIE is an all-oral antiviral treatment consisting of the fixed-dose combination of ombitasvir/paritaprevir/ritonavir (12.5/75/50 mg) taken as 2 tablets once daily and taken with food, which is co-administered with weight-based RBV (1000mg or 1200mg in divided doses, twice daily), taken with food. The combination of two direct-acting antivirals, each with distinct mechanisms of action, targets and inhibits specific HCV proteins in the viral replication process.

### **About AbbVie Care**

Canadians prescribed TECHNIVIE 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.

For more information, call 1-844-471-CARE (2273) or consult [www.abbviecare.ca](http://www.abbviecare.ca).

### **Important Safety Information<sup>4</sup>**

TECHNIVIE (ombitasvir/paritaprevir/ritonavir tablets) is a prescription medicine used with ribavirin to treat adults with genotype 4 chronic (lasting a long time) hepatitis C (hep C) virus infection without cirrhosis.

To help avoid side effects and make sure you are using your medicines correctly, talk to your doctor before you take TECHNIVIE. Talk about any health problems you may have, including if you:

- are taking birth control medicines of any kind or using a medicine that has ethinyl estradiol.

Ethinyl estradiol is usually found in birth control pills. However, not all birth control pills have ethinyl estradiol. You must not use medicines that have ethinyl estradiol while taking TECHNIVIE. Your doctor will ask you to stop or change to a different type of birth control while you are taking TECHNIVIE.

- have had a liver transplant.
- have liver problems other than HCV infection.
- are breastfeeding or plan to breastfeed. It is not known if TECHNIVIE passes into your breast milk. You and your doctor should decide if you will take TECHNIVIE or breastfeed. You should not do both.

#### *Pregnancy and Birth Control*

- Females must have a negative pregnancy test before starting TECHNIVIE and ribavirin, every month while on the medicine, and for 6 months after stopping them.
- You or your partner should not become pregnant while taking TECHNIVIE with ribavirin and for 6 months after you have stopped taking them.
- You and your partner must use 2 kinds of birth control while taking TECHNIVIE and ribavirin and for 6 months after you have stopped taking them.
- Talk to your doctor about the kind of birth control that you can use.
- If you or your partner becomes pregnant while taking TECHNIVIE and ribavirin or within 6 months after you stop taking them, tell your doctor right away.

Other warnings you should know about:

Rises in liver tests have occurred when TECHNIVIE was taken in studies. Contact your doctor right away if you have symptoms like those listed below since these may mean you have a serious problem with your liver:

- loss of appetite (do not feel like eating),
- stomach ache,
- nausea (feeling sick in the stomach),
- vomiting,
- feeling tired or weak,
- yellowing of the skin and eyes,
- dark urine and pale stool.

It is not known if taking TECHNIVIE is safe or will work in children under 18 years of age.

Your doctor may do blood tests before you start taking, and while you are on your medicines. This is to help check if the medicines are working for you.

Tell your doctor all the medicines, drugs, vitamins and minerals, natural supplements or alternative medicines you are already taking, as interactions are possible with TECHNIVIE.

The complete TECHNIVIE Product Monograph is available on 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).

### **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.

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<sup>1</sup> CATIE.

<http://www.catie.ca/en/treatmentupdate/treatmentupdate-202/hepatitis-c-virus/simeprevir-interferon-ribavirin-hcv-genotype-4>

Accessed on November 10, 2015

<sup>2</sup> PUBMED. Hepatitis C genotype 4: What we know and what we don't yet know. Kamal SM, Nasser IA.

<http://www.ncbi.nlm.nih.gov/pubmed/18240152>

Accessed on November 10, 2015

<sup>3</sup> AASLD/IDSA/IAS–USA. When and in Whom to Initiate HCV Therapy.

<http://www.hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy>

Accessed on November 10, 2015

<sup>4</sup> TECHNIVIE (ombitasvir/paritaprevir/ritonavir tablets) Product Monograph. Date of Preparation: October 20, 2015

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

Accessed on November 10, 2015

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