



## News Release

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**VICTRELIS™ Approved in Canada:  
First in new class of drugs to significantly improve clearance of chronic  
hepatitis C virus from the body**

MONTREAL, QUEBEC, August 3, 2011 – Merck announced today that VICTRELIS™ (boceprevir) has been approved in Canada for the treatment of chronic hepatitis C (CHC) genotype 1 infection in combination with the current standard therapy, peginterferon alpha and ribavirin (peg/riba), in adult patients (18 years and older) with compensated liver disease, including cirrhosis, who are previously untreated or who have failed previous therapy.<sup>1</sup>

“If patients receive hepatitis C treatment at an early stage, they may be able to avoid the most severe consequences of their disease – cirrhosis, liver cancer or liver failure requiring a liver transplant,” says Dr. Morris Sherman, Chairman of the Canadian Liver Foundation.

“Up until now, currently available therapies have only been effective for a small percentage of hepatitis C patients. Boceprevir is one of a new generation of drugs that mark a significant step forward in hepatitis C treatment. For patients who have not yet been treated or have not responded to previous treatment, this is an exciting development that offers them greater hope for a cure.”

**Merck is Committed to Hepatitis C Patient Support**

“Merck has been developing innovative therapies for the treatment of CHC infection for nearly three decades, and we are very proud to add boceprevir to our treatment options against this infection,” says Josée Brisebois, PhD, Director of Medical Affairs at Merck Canada. “Merck understands the treatment of CHC genotype 1 infection weighs heavily, not only on those infected, but also on their health care providers. We have a support program in place for patients on peginterferon alpha and ribavirin, the current standard treatment, and will be adding support for boceprevir to the program.”

Elements of the current hepatitis C patient support program include: nurses to provide support and guidance to patients and financial assistance for those who qualify based on specific income and health-related criteria.

### **Adding VICTRELIS™ Can Help Clear Virus**

Boceprevir is a first-in-class oral hepatitis C virus (HCV) protease inhibitor that when added to peg/riba, can significantly increase a patient's chance of clearing the virus from the body.<sup>2,3</sup> Two studies, HCV RESPOND-2 and HCV SPRINT-2, published earlier this year in *The New England Journal of Medicine*, found that boceprevir tripled the treatment response in patients who have previously failed treatment<sup>4</sup> and nearly doubled the treatment response in previously untreated patients.<sup>5</sup>

### **Adding VICTRELIS™ May Shorten Therapy**

"The improved response rates when you add boceprevir to current standard therapy are really significant when you consider the challenges associated with treating patients who have chronic hepatitis C genotype 1 infection," says Dr. Stephen Shafran, Professor, Division of Infectious Diseases, Department of Medicine at the University of Alberta. "With this combination of drugs the majority of patients will be able to clear the virus. Many of them will also be able to finish therapy faster, which is important as treatment side effects can be devastating."

Response-guided therapy (RGT) – a new treatment paradigm described in the pivotal clinical studies HCV RESPOND-2 and HCV SPRINT-2 – may cut 12<sup>6</sup> or 20 weeks<sup>7</sup> from the standard 48 weeks of treatment for previously treated patients or untreated patients, respectively.

"The drugs made me feel so sick that I had to stop my first treatment after several months. No one can understand how bad the side effects can be unless you've experienced them first-hand," says Tina Ferstman, a Montréal resident who contracted the hepatitis C virus from a former surgery. "I got through my therapy the second time around because I was better prepared. Unfortunately, even though I completed the treatment, I wasn't cured."

Common side effects of treatment include fatigue, headache, nausea, anemia and bad taste (dysgeusia).<sup>8</sup>

## **The Burden of CHC in Canada**

Long-term complications of hepatitis C are costly. Three-quarters of those who acquire HCV become chronically infected and 14 to 19 per cent will develop cirrhosis within 20 years, which may lead to liver failure, liver cancer (hepatocellular carcinoma) and death.<sup>9</sup> The incidence of serious complications from chronic hepatitis C (CHC) in Canada are predicted to continue to rise significantly up to the year of 2027,<sup>10</sup> not taking into account the possible impact of the expanded use of currently available antiviral medications (e.g., pegylated interferon and ribavirin) nor the potential impact of new, more effective regimens.<sup>11</sup>

VICTRELIS™ is now available and the list price is \$1,050.00 per week.

## **About Merck**

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our medicines, vaccines, biologic therapies, and consumer and animal products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information about our operations in Canada, visit [www.merck.ca](http://www.merck.ca).

## **Forward-Looking Statement**

This news release includes "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. Such statements may include, but are not limited to, statements about the benefits of the merger between Merck and Schering-Plough, including future financial and operating results, the combined company's plans, objectives, expectations and intentions and other statements that are not historical facts. Such statements are based upon the current beliefs and expectations of Merck's management and are subject to significant risks and uncertainties. Actual results may differ from those set forth in the forward-looking statements.

The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements: the possibility that the expected synergies from the merger of Merck and Schering-Plough will not be realized, or will not be realized within the expected time period; the impact of pharmaceutical industry regulation and health care legislation; the risk that the businesses will not be integrated successfully; disruption from the merger making it more difficult to maintain business and operational relationships;

Merck's ability to accurately predict future market conditions; dependence on the effectiveness of Merck's patents and other protections for innovative products; the risk of new and changing regulation and health policies in the United States and internationally and the exposure to litigation and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck's 2010 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site ([www.sec.gov](http://www.sec.gov)).

- 30 -

### **References:**

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- <sup>1</sup> VICTRELIS™, Product Monograph, July 27, 2011, p. 3.
  - <sup>2</sup> Poordad, F., *et al.*, for the SPRINT-2 Investigators. Boceprevir for Untreated Chronic HCV Genotype 1 Infection. *N Engl J Med* 2011; 364:1195-1206, page 1195.
  - <sup>3</sup> Bacon, B.R., *et al.*, for the HCV RESPOND-2 Investigators. Boceprevir for Previously Treated Chronic HCV Genotype 1 Infection. *N Engl J Med* 2011; 364:1207-1217, p. 1207.
  - <sup>4</sup> *Ibid.*
  - <sup>5</sup> Poordad, F., *et al.*, for the SPRINT-2 Investigators. Boceprevir for Untreated Chronic HCV Genotype 1 Infection. *N Engl J Med* 2011; 364:1195-1206, p. 1200-1201.
  - <sup>6</sup> Bacon, B.R., *et al.*, for the HCV RESPOND-2 Investigators. Boceprevir for Previously Treated Chronic HCV Genotype 1 Infection. *N Engl J Med* 2011; 364:1207-1217, p. 1209.
  - <sup>7</sup> Poordad, F., *et al.*, for the SPRINT-2 Investigators. Boceprevir for Untreated Chronic HCV Genotype 1 Infection. *N Engl J Med* 2011; 364:1195-1206, p. 1197.
  - <sup>8</sup> VICTRELIS™, Product Monograph, July 27, 2011, p. 8.
  - <sup>9</sup> Krajden M, Kuo M, Zagorski B, Alvarez M, Yu A, Krahn M. "Health care cost associated with hepatitis C: Longitudinal cohort study. *Can J Gastroenterol* 2010;24(12):717-726, p. 717.
  - <sup>10</sup> Remis RS. Modelling the incidence and prevalence of hepatitis c infection and its sequelae in Canada, 2007 . Public Health Agency of Canada website [updated 2007; cited 2011 Jan 4]. Available from: <http://www.phac-aspc.gc.ca/sti-its-surv-epi/model/pdf/model07-eng.pdf>, p. 5.
  - <sup>11</sup> Remis RS. Modelling the incidence and prevalence of hepatitis c infection and its sequelae in Canada, 2007 . Public Health Agency of Canada website [updated 2007;cited 2011 Jan 4]. Available from: <http://www.phac-aspc.gc.ca/sti-its-surv-epi/model/pdf/model07-eng.pdf>, p. 46.