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**Boceprevir based therapy cleared the hepatitis C virus in 38 per cent of patients who had failed to respond to previous treatment**

***Data Presented at the American Association for the Study of Liver Diseases 2011 Annual Meeting***

MONTREAL, QUEBEC, Nov. 7, 2011 – Today Merck announced results of an interim analysis from the PROVIDE study, an open-label study examining the efficacy of VICTRELIS™ (boceprevir), the company's first-in-class, oral hepatitis C virus (HCV) protease inhibitor, in combination with peginterferon alpha and ribavirin (P/R) in adult patients with chronic HCV genotype 1 who had a null response to prior P/R therapy. These patients are significantly less likely to respond to subsequent treatments. In this interim analysis, 38 per cent (16/42) of prior null responders achieved a sustained virologic response (SVR), meaning they were able to clear the virus from the body, when treated with boceprevir in combination with P/R. These results were presented at the 62<sup>nd</sup> Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in San Francisco.

“The null responders are the toughest patient group to treat and until now, there was not much optimism that they could ever clear the hepatitis C virus,” says Eric Yoshida, M.D., study investigator and Professor of Medicine at the University of British Columbia. “The PROVIDE study definitely demonstrates that boceprevir with peginterferon and ribavirin can provide these patients with hope for the future.”

### **About the PROVIDE Study**

The PROVIDE study is an ongoing, open-label, single-arm, multicenter rollover study for patients who participated in the P/R control arms of the Phase II and Phase III studies for boceprevir and failed to achieve SVR. Of these, 48 patients from the two pivotal Phase III trials for boceprevir (HCV SPRINT-2 and HCV RESPOND-2) met the traditional definition for null response (less than a 2 log HCV-RNA decline at treatment week 12). These patients were retreated with a 4-week lead-in of peginterferon alpha-2b (1.5 mcg/kg/week) and ribavirin (600-1,400 mg/day), followed by the addition of boceprevir (800 mg three times a day) for 44 weeks. Three of these patients discontinued treatment during the 4-week P/R lead-in phase prior to receiving boceprevir, two patients are currently on treatment and one patient is currently in the follow-up phase. Among patients completing treatment and follow-up, 38 per cent (16/42) achieved SVR and 16 per cent (3/19) relapsed.

### **Hepatitis C in Canada**

An estimated 250,000 individuals in Canada are infected with HCV and there are 3,200 to 5,000 newly infected individuals each year<sup>1</sup>. HCV damages the liver and may lead to serious complications, including death, when left untreated<sup>2</sup>. It is the leading cause of liver transplants in Canada<sup>3</sup>.

There is a stigma linked with hepatitis C infection because of its association with injection drug use<sup>4</sup>, which poses a major barrier to detection and treatment. As a result, those who are undiagnosed may continue to unknowingly spread the virus to others<sup>5</sup>.

### **Boceprevir in Canada**

Boceprevir (VICTRELIS™) was approved for use in Canada in July of this year for the treatment of chronic hepatitis C genotype 1 infection, in combination with peginterferon alpha and ribavirin, in adult patients (18 years of age and older) with compensated liver disease, including cirrhosis, who are previously untreated or who have failed previous peginterferon and ribavirin therapy<sup>6</sup>.

Common side effects of combination treatment include fatigue, anemia, nausea, headache and bad taste (dysgeusia)<sup>7</sup>.

### **Merck's global commitment to advancing hepatitis therapy**

Merck is committed to building on its strong legacy in the field of viral hepatitis by continuing to discover, develop and deliver vaccines and medicines to help prevent and treat viral hepatitis. In hepatitis C, company researchers developed the first approved therapy for chronic HCV in 1991 and the first combination therapy in 1998. In addition to ongoing studies with boceprevir extensive research efforts are underway to develop additional innovative oral therapies for viral hepatitis C treatment.

### **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)).

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<sup>1</sup> Canadian Institutes of Health Research. About the Hep C Research Initiative. <http://www.cihr-irsc.gc.ca/e/38855.html>. Accessed November 2, 2011.

<sup>2</sup> Public Health Agency of Canada. <http://www.phac-aspc.gc.ca/hepc/pubs/multiling-hepc/index-eng.php>. Accessed November 2, 2011.

<sup>3</sup> Canadian Liver Foundation. [http://www.liver.ca/Liver\\_Disease/](http://www.liver.ca/Liver_Disease/). Accessed November 2, 2011.

<sup>4</sup> HCV Advocate. Stigma and Hepatitis C. [http://www.hcvadvocate.org/hepatitis/factsheets\\_pdf/Stigma\\_09.pdf](http://www.hcvadvocate.org/hepatitis/factsheets_pdf/Stigma_09.pdf). Accessed on November 2, 2011.

<sup>5</sup> Health Canada. <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/diseases-maladies/hepc-eng.php>. Accessed on November 2, 2011.

<sup>6</sup> VICTRELIS<sup>TM</sup>, Product Monograph, July 27, 2011, p. 3.

<sup>7</sup> VICTRELIS<sup>TM</sup>, Product Monograph, July 27, 2011, p. 8.