



News Release

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FOR IMMEDIATE RELEASE

In Pivotal Phase III Studies, Merck's Oral Investigational Medicine Boceprevir Helped Majority of Patients with Chronic Hepatitis C Genotype 1 Infection Achieve Sustained Virologic Response (SVR), the Primary Endpoint of the Studies

MONTREAL, QUEBEC, Aug. 11, 2010 – Merck has reported that two pivotal Phase III registration studies for boceprevir, its investigational oral hepatitis C protease inhibitor, have been completed and met the primary endpoints: in both studies in patients with chronic hepatitis C virus (HCV) genotype 1 infection, the addition of boceprevir to treatment with peginterferon alfa-2b and ribavirin (known in Canada as PEGETRON[®] and henceforth referred to as peg2b/riba) significantly increased the number of patients who achieved sustained virologic response (SVR; defined as undetectable virus levels 24 weeks after the end of treatment), compared to control groups that received Peg2b/riba plus placebo.

Boceprevir, in combination with Peg2b/riba, is being studied for the treatment of patients with chronic hepatitis C genotype 1 who have previously been treated (treatment-failure; HCV RESPOND-2) and in patients who are new to treatment (treatment-naïve; HCV SPRINT-2). Abstracts for boceprevir studies have already been submitted for presentation at a medical meeting later this year, and additional abstracts have also recently been submitted.

“Chronic hepatitis C remains a significant and potentially life-threatening disease for which new approaches are needed,” said Dr. Frank Anderson, MD, FRCPC, a Canadian investigator for both the HCV SPRINT-2 study and the HCV RESPOND-2 study. “In both treatment-naïve patients and those who have failed prior hepatitis C therapy – a group that is often the hardest to treat, the significant increase in SVR

achieved in the boceprevir arm of these studies builds on our body of knowledge about this new molecule.”

An estimated 250,000 individuals are infected with HCV in Canada¹ and in 2007, there were nearly 8,000 newly infected individuals.² It is the leading cause of liver transplants in Canada.³ Boceprevir works through a novel mechanism, by inhibiting the function of a viral protein called ‘protease’ that the virus needs to replicate.

The HCV RESPOND-2 and HCV SPRINT-2 studies each evaluated two treatment strategies with boceprevir: 48 weeks of treatment for all patients (4-week lead-in with 1.5 mcg/kg/week of peginterferon alfa-2b and an investigational dose of 600-1,400 mg/day of ribavirin, followed by the addition of boceprevir 800 mg three times a day for 44 weeks), and response-guided therapy, in which patients with undetectable virus at week 8 and again at certain points later in the studies were able to stop all treatment at 36 weeks in HCV RESPOND-2 and at 28 weeks in HCV SPRINT-2. Patients who did not meet these criteria continued treatment with Peg2b/riba alone for a total treatment duration of 48 weeks. Control groups in the studies received Peg2b/riba at the doses described above plus placebo for 48 weeks.

The HCV RESPOND-2 study was conducted in 403 patients who failed prior therapy at U.S., Canadian and international sites, and patients were randomized into the three groups (48 weeks control; 48 weeks control plus boceprevir; control plus boceprevir using response-guided therapy) at a 1:2:2 ratio. In the boceprevir 48-week treatment group, 66 percent of patients achieved SVR, and in the boceprevir response-guided therapy group, 59 percent of patients achieved SVR, compared to 21 percent of patients in the control group ($p < 0.0001$ for both, intent-to-treat analysis).

In the HCV SPRINT-2 study, 1,097 treatment-naïve patients at U.S., Canadian and international sites were enrolled in two separate cohorts, one with 938 non-black patients and the other with 159 black patients. Patients were randomized into the three treatment groups (48 weeks control; 48 weeks control plus boceprevir; control plus boceprevir using response-guided therapy) at a ratio of 1:1:1. In the study overall, 66 percent of patients in the boceprevir 48-week treatment group achieved SVR, and 63 percent of patients in the response-guided therapy group achieved SVR, compared to 38 percent of patients in the control group ($p < 0.0001$ for both, intent-to-treat analysis).

As specified by the HCV SPRINT-2 study protocol, results for the non-black and black patient cohorts were analyzed separately. Several previous studies have shown that black patients have a lower response to HCV treatment than non-black patients.⁴⁻⁶

Among the non-black patients in the boceprevir 48-week treatment group, 69 percent achieved SVR, and in the response-guided therapy group, 67 percent of patients achieved SVR, compared to 40 percent in the control group ($p < 0.0001$ for both, intent-to-treat analysis). Among the black patients, 53 percent of patients in the 48-week treatment group and 42 percent of patients in the response-guided therapy group achieved SVR, compared to 23 percent in the control group ($p = 0.004$ and $p = 0.044$, respectively, intent-to-treat analysis).

“Every patient with HCV responds differently to treatment, which is why the response-guided therapy approach used in both of these studies is so significant,” said Dr. Stephen Shafran, MD, FRCPC, FACP, University of Alberta and a SPRINT-2 investigator. “In the patient populations who had undetectable levels of virus at certain points in both studies, total treatment duration to achieve SVR was shorter than with the control group. Further, if we look at the overall SVR ratios achieved in RESPOND-2 and SPRINT-2, we have up to a three-fold and a 1.74-fold increase in SVR for treatment-experienced and treatment-naïve patients respectively, which as a clinician is another exciting result.”

In the HCV RESPOND-2 study, the five most common treatment-emergent adverse events reported for the boceprevir 48-week treatment group, boceprevir response-guided therapy group and control group, respectively, were: fatigue (57, 54, and 50 percent), headache (40, 43 and 49 percent), nausea (42, 44 and 38 percent), anemia (47, 43 and 20 percent) and dysgeusia (bad taste) (45, 43 and 11 percent). Treatment discontinuations due to anemia were 3 percent and 0 percent for the boceprevir groups, respectively, compared to 0 percent for the control group. Treatment discontinuations due to adverse events overall were 12 percent and 8 percent for the boceprevir groups, respectively, compared to 3 percent for the control group.

In the HCV SPRINT-2 study, the five most common treatment-emergent adverse events reported for the boceprevir 48-week treatment group, boceprevir response-guided therapy group and control group, respectively, were: fatigue (57, 53 and 60 percent), headache (46, 46 and 42 percent), nausea (43, 48 and 42 percent), anemia (49, 49 and 29 percent) and pyrexia (fever) (32, 33 and 33 percent). Treatment discontinuations due to anemia were 2 percent for each of the boceprevir groups compared to 1 percent for the control group. Treatment discontinuations due to adverse events overall were 16 percent and 12 percent for the boceprevir groups, respectively, compared to 16 percent for the control group.

About the studies

The HCV RESPOND-2 study was conducted in patients chronically infected with hepatitis C genotype 1 who failed prior therapy with Peg2b/riba including those who had experienced prior relapse or who were prior non-responders, and the HCV SPRINT-2 study was conducted in previously untreated (treatment-naïve) patients chronically infected with hepatitis C genotype 1. Approximately 25 percent of patients in each of the studies had less than a 1 log decrease in viral load after the 4-week Peg2b/riba lead-in period.

Sustained virologic response (SVR), the protocol-specified primary efficacy endpoint, is defined as achievement of undetectable HCV-RNA at 24 weeks after the end of treatment in all randomized patients treated with any study medication (Roche's TaqMan LLD=9.3 IU/mL). Per protocol, if a patient did not have a 24-week post-treatment assessment, the patient's 12-week post-treatment assessment was utilized.

In the HCV RESPOND-2 study, patients in the response-guided therapy arm who had undetectable virus at treatment week 8 and week 12 received a total of 36 weeks of therapy (lead-in with Peg2b/riba followed by the addition of boceprevir for 32 weeks); patients with detectable virus at week 8, but undetectable virus at week 12, stopped boceprevir treatment at week 36 and continued on Peg2b/riba alone for an additional 12 weeks, for a total treatment duration of 48 weeks. Patients in any arm of the study who had detectable virus at week 12 were considered treatment failures and discontinued treatment.

In the HCV SPRINT-2 study, patients in the response-guided therapy group of the study who had undetectable virus at treatment week 8 through week 24 received a total of 28 weeks of therapy (lead-in with Peg2b/riba followed by the addition of boceprevir for 24 weeks); patients with detectable virus at week 8, but undetectable virus at week 24, stopped boceprevir treatment at week 28 and continued on Peg2b/riba alone for a total treatment duration of 48 weeks. Patients in any arm of the study who had detectable virus at week 24 were considered treatment failures and discontinued treatment.

Merck's commitment to advancing hepatitis therapy

Merck is committed to building on its strong legacy in the hepatitis field by continuing to discover, develop and deliver vaccines and medicines to help prevent and treat viral hepatitis. Extensive research efforts are underway to develop differentiated

oral therapies that bring innovation to hepatitis care. Market authorization has not yet been obtained in Canada for boceprevir.

About Merck

Today's Merck is a global healthcare leader. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and consumer care and animal health 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, visit www.merck.ca.

Forward Looking Statement

This information 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 proposed 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 and Schering-Plough’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, due to, among other things, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry; 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 U.S. 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 2008 Annual Report on Form 10-K, Schering-Plough's Quarterly Report on Form 10-Q for the quarterly period ended Sept. 30, 2009, the proxy statement filed by Merck on June 25, 2009 and each company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

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Endnotes

1. Health Canada. <http://www.phac-aspc.gc.ca/hepc/faq-eng.php> . Accessed Aug. 6, 2010.
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