



NEWS RELEASE

# Merck Announces Initiation of Clinical Development Collaboration with Roche To Evaluate Investigational Combination Regimens for the Treatment of Chronic Hepatitis C Genotype 1 Infection

12/15/2011

New Clinical Trial Will Evaluate an Investigational Therapeutic Regimen with VICTRELIS™ (boceprevir)

Merck (NYSE: MRK), known as MSD outside the United States and Canada, announced today that Merck, in collaboration with Roche (SIX: RO, ROG; OTCQX: RHHBY), has initiated the first of a series of planned clinical trials to examine novel combinations of marketed and investigational medicines to expedite the availability of potential new treatment regimens for patients with chronic hepatitis C virus (HCV) genotype 1 infection. Clinical development collaboration is part of the overarching strategic agreement between Merck and Roche to improve treatment, diagnosis and awareness of chronic HCV in developed and emerging markets.

"VICTRELIS is the first in a new class of medicines for the treatment of chronic HCV genotype 1 infection, and when used in combination with peginterferon alfa, can significantly increase a patient's chance of achieving undetectable levels of the virus," said Eliav Barr, M.D., vice president, Infectious Diseases Project Leadership and Management, Merck Research Laboratories. "The start of this new study is an important milestone in our collaboration with Roche as we work to build on the innovative platform VICTRELIS provides by evaluating it in combination therapy with new investigational medicines for the treatment of chronic HCV genotype 1 infection, and also emphasizes our ongoing commitment to seeking novel treatment options for patients with chronic HCV."

The first trial is designed to provide clinical data on the use of VICTRELIS™ (boceprevir), an oral HCV NS3/4A protease inhibitor, in combination with mericitabine (RO5024048), Roche's investigational oral HCV NS5B

nucleoside polymerase inhibitor, Pegasys® (pegylated interferon alfa-2a) and Copegus® (ribavirin), in adult patients with chronic HCV genotype 1 infection who had a null response to prior peginterferon alfa and ribavirin therapy (less than a 2 log HCV-RNA decline at treatment week 12). The Phase II study, called DYNAMO 1, plans to recruit patients at 25 sites globally. For further details of the clinical trial please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov), or contact (888) 662-6728 (U.S. only) or [Genentechclinicaltrials@druginfo.com](mailto:Genentechclinicaltrials@druginfo.com).

#### Indications and usage for VICTRELIS

VICTRELIS was approved by the U.S. Food and Drug Administration (FDA) on May 13, 2011 for the treatment of chronic hepatitis C virus (HCV) genotype 1 (G1) infection, in combination with peginterferon alfa and ribavirin (P/R), in adult patients (18 years and older) with compensated liver disease, including cirrhosis, who are previously untreated or who have failed previous interferon and ribavirin therapy.

The following points should be considered when initiating VICTRELIS for treatment of chronic HCV infection:

-- VICTRELIS must not be used as monotherapy and should only be used in combination with peginterferon alfa and ribavirin.

-- VICTRELIS efficacy has not been studied in patients who have previously failed therapy with a treatment regimen that includes VICTRELIS or other HCV NS3/4A protease inhibitors.

-- VICTRELIS in combination with peginterferon alfa and ribavirin has not been studied in patients documented to be historical null responders (less than a 2 log HCV-RNA decline by treatment week 12) during prior therapy with peginterferon alfa and ribavirin. The clinical studies included patients who were poorly interferon responsive. Patients with less than 0.5 log HCV-RNA decline in viral load at treatment week 4 with peginterferon alfa plus ribavirin alone are predicted to have a null response (less than a 2 log viral load decline by treatment week 12) to peginterferon alfa and ribavirin therapy.

-- Poorly interferon responsive patients who were treated with VICTRELIS in combination with peginterferon alfa and ribavirin have a lower likelihood of achieving a sustained virologic response (SVR), and a higher rate of detection of resistance-associated substitutions upon treatment failure, compared to patients with a greater response to peginterferon alfa and ribavirin.

#### Important safety information about VICTRELIS

All contraindications to peginterferon alfa and ribavirin also apply since VICTRELIS must be administered with peginterferon alfa and ribavirin. Because ribavirin may cause birth defects and fetal death, VICTRELIS in

combination with peginterferon alfa and ribavirin is contraindicated in pregnant women and in men whose female partners are pregnant. Avoid pregnancy in female patients and female partners of male patients. Patients must have a negative pregnancy test prior to therapy; have monthly pregnancy tests; and use two or more forms of effective contraception, including intrauterine devices and barrier methods, during treatment and for at least 6 months after treatment has concluded. Systemic hormonal contraceptives may not be as effective in women while taking VICTRELIS and concomitant ribavirin.

VICTRELIS is contraindicated in coadministration with drugs that are highly dependent on CYP3A4/5 for clearance, and for which elevated plasma concentrations are associated with serious and/or life-threatening events. VICTRELIS also is contraindicated in coadministration with potent CYP3A4/5 inducers where significantly reduced VICTRELIS plasma concentrations may be associated with reduced efficacy. Drugs that are contraindicated with VICTRELIS include: alfuzosin, carbamazepine, phenobarbital, phenytoin, rifampin, dihydroergotamine, ergonovine, ergotamine, methylergonovine, cisapride, St. John's Wort (*hypericum perforatum*), lovastatin, simvastatin, drospirenone, Revatio® (sildenafil) or Adcirca® (tadalafil) (when used for the treatment of pulmonary arterial hypertension), pimozone, triazolam, and orally administered midazolam.

Anemia and neutropenia have been reported with peginterferon alfa and ribavirin therapy. The addition of VICTRELIS to peginterferon alfa and ribavirin is associated with an additional decrease in hemoglobin concentrations compared to peginterferon alfa and ribavirin alone and/or may result in worsening of neutropenia associated with peginterferon alfa and ribavirin therapy alone. Dose reduction or discontinuation of peginterferon alfa and/or ribavirin may be required. Dose reduction of VICTRELIS is not recommended. VICTRELIS must not be administered in the absence of peginterferon alfa and ribavirin.

Complete blood counts (with white blood cell differential counts) must be conducted in all patients prior to initiating combination therapy with VICTRELIS. Complete blood counts should be obtained at treatment weeks 4, 8 and 12, and should be monitored closely at other time points, as clinically appropriate.

The most commonly reported adverse reactions (greater than 35 percent) in clinical trials in adult patients receiving the combination of VICTRELIS with peginterferon alfa and ribavirin were fatigue, anemia, nausea, headache and dysgeusia. Of these commonly reported adverse reactions, fatigue, anemia, nausea, and dysgeusia occurred at rates greater than or equal to 5 percent above the rates for peginterferon alfa and ribavirin alone in either clinical study. The incidence of these adverse reactions in previously untreated patients who were treated with combination therapy with VICTRELIS compared with peginterferon and ribavirin alone were: fatigue (58 vs. 59 percent), anemia (50 vs. 30 percent), nausea (46 vs. 42 percent) and dysgeusia (35 vs. 16 percent), respectively. The incidence of these adverse reactions in previous treatment-failure patients who were treated with combination therapy with VICTRELIS compared with peginterferon and ribavirin alone were: fatigue (55 vs. 50 percent), anemia

(45 vs. 20 percent), nausea (43 vs. 38 percent) and dysgeusia (44 vs. 11 percent), respectively.

VICTRELIS is a strong inhibitor of CYP3A4/5 and is partly metabolized by CYP3A4/5. The potential for drug-drug interactions must be considered prior to and during therapy.

Please see U.S. prescribing information at:

**[http://www.merck.com/product/usa/pi\\_circulars/v/victrelis/victrelis\\_pi.pdf](http://www.merck.com/product/usa/pi_circulars/v/victrelis/victrelis_pi.pdf)**.

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 VICTRELIS, extensive research efforts are underway to develop additional innovative oral therapies for viral hepatitis care.

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 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.com](http://www.merck.com)** and connect with us on Twitter, Facebook and YouTube.

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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Please see Prescribing Information for VICTRELIS at

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