Merck Announces New Data Analyses for VICTRELIS™ (boceprevir) will be Presented at The American Association for the Study of Liver Diseases 2011 Annual Meeting

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WHITEHOUSE STATION, N.J.--(BUSINESS WIRE)--Merck (NYSE: MRK), known as MSD outside of the United States and Canada, announced today that several new analyses from Phase III studies of VICTRELIS™ (boceprevir), the company’s first-in-class, oral hepatitis C virus (HCV) NS3/4A protease inhibitor will be presented at the 62nd Annual Meeting of the American Association for the Study of Liver Diseases (AASLD). The meeting will be held Nov. 4-8 in San Francisco. Presentations will include results from the Phase III PROVIDE study, which evaluated the efficacy of VICTRELIS in combination with peginterferon alfa and ribavirin in adult patients with chronic HCV genotype 1 infection who had prior null response to treatment with peginterferon alfa and ribavirin alone.

“Merck looks forward to sharing data with the scientific community at this year’s AASLD to inform the continuing fight against chronic hepatitis C”

More than 30 abstracts highlighting Merck medicines and investigational therapies for chronic HCV will be presented at AASLD, including four oral presentations and 14 posters for VICTRELIS. One poster has been selected as a Presidential Poster of Distinction.

New data also will be presented on the efficacy and safety of Merck’s MK-5172, an investigational once-daily, second-generation oral HCV NS3/4A protease inhibitor, in patients chronically infected with HCV genotypes 1 and 3.

"Merck looks forward to sharing data with the scientific community at this year's AASLD to inform the continuing fight against chronic hepatitis C," said Roger J. Pomerantz, M.D., F.A.C.P., senior vice president, Infectious Diseases, Merck Research Laboratories.

The abstracts were published today and can be accessed on the AASLD website. For program information, please visit https://www.aasld.org.

Key presentations for VICTRELIS

Efficacy of Boceprevir in Patients with Null Responses to Peginterferon/Ribavirin:

The PROVIDE study. Vierling, J. et al. Poster 931. Sunday, Nov. 6, 8:00 a.m. – 5:30 p.m. Moscone West Convention Center Poster Hall

Treatment-Naive Black Patients Treated with Boceprevir Combined with Peginterferon Alfa-2b + Ribavirin: Results from HCV SPRINT-2. McCone, J. et al. Poster 981. Sunday, Nov. 6, 8:00 a.m. – 5:30 p.m.


Genotypic and Phenotypic Correlates of Resistance in HCV Genotype 1a and 1b Infected Patients Treated with Boceprevir Plus Peginterferon Alpha and Ribavirin. Ogert, R.A. et al. Poster 927. Sunday, Nov. 6, 8:00 a.m. – 5:30 p.m. Moscone West Convention Center Poster Hall. Selected as a Presidential Poster of Distinction

Other key Merck presentations

IL28B genotype predicted for >/=1 log10 IU/mL reduction in serum HCV RNA after 4 weeks of peginterferon and ribavirin therapy: implications for the use of the lead-in strategy for DAA-based treatment regimens. Thompson, A.J. et al. Abstract #157. Oral Presentation: Monday, Nov. 7, 3:00 -3:15 p.m., Moscone West Convention Center, Rooms 2006-2008

Safety and Antiviral Activity of MK-5172, a Next Generation HCV NS3/4A Protease Inhibitor with a Broad HCV Genotypic Activity Spectrum and Potent Activity Against Known Resistance Mutants, in Genotype 1 and 3 HCV-Infected Patients. Petry, A. et al. Poster 346. Saturday, Nov. 5, 2:00 p.m. – 7:30 p.m. Moscone West Convention Center Poster Hall
MK-5172, a Second-Generation HCV NS3/4A Protease Inhibitor, is Active against Common Resistance Associated Variants (RAVs) and Exhibits Cross-Genotype Activity. Graham, D. et al. Poster 370. Saturday, Nov. 5, 2:00 p.m. – 7:30 p.m. Moscone West Convention Center Poster Hall

**Indications and usage for VICTRELIS**

VICTRELIS was approved by the U.S. Food and Drug Administration (FDA) on May 13 for the treatment of chronic hepatitis C genotype 1 infection, in combination with peginterferon alfa 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 interferon and ribavirin therapy.

The following points should be considered when initiating VICTRELIS for treatment of chronic hepatitis C 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 HCV-RNA 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.

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 boceprevir 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), pimozide, triazolam, and midazolam (orally administered).

Anemia has 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. The addition of VICTRELIS may result in a worsening of neutropenia associated with peginterferon alfa and ribavirin alone. Complete blood counts should be obtained pretreatment, and at treatment weeks 4, 8 and 12, and should be monitored closely at other time points, as clinically appropriate. If a patient has a serious adverse reaction potentially related to peginterferon alfa and ribavirin therapy, the peginterferon alfa and/or ribavirin dose should be reduced or discontinued. VICTRELIS must not be administered in the absence of peginterferon alfa and ribavirin. Dose reduction of VICTRELIS is not recommended.

The most commonly reported adverse reactions (greater than 35 percent) in clinical trials in adult patients receiving the combination of VICTRELIS with peginterferon alfa-2b 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 received VICTRELIS combination therapy compared with peginterferon and ribavirin alone were: fatigue (58 vs. 59 percent), anemia (50 vs. 30 percent), nausea (46 vs. 42 percent), dysgeusia (35 vs. 16 percent), respectively. The incidence of these adverse reactions in previously treated patients who received VICTRELIS combination therapy compared with peginterferon and ribavirin alone were: fatigue (55 vs. 50 percent), anemia (45 vs. 20 percent), nausea (43 vs. 38 percent), 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.


**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 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 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 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 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 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).


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