P.O. Box 1000
North Wales, PA 19454-1099

January 2015

SUBJECT: Merck Voluntarily Discontinuing VICTRELIS® (boceprevir) 200 mg Capsules

Dear Pharmacy Professional:

We would like to inform you that Merck has decided to voluntarily discontinue the manufacture and distribution of VICTRELIS in the United States by December 2015. Please note that this is a business decision by Merck. This decision is not based on any safety or efficacy findings with this product. Due to the scientific advancement, changes in treatment practices, and the consequent reduction in the demand for VICTRELIS, Merck plans to discontinue commercial supply of VICTRELIS in the United States.

Merck remains committed to the treatment of chronic hepatitis C. To ensure all patients currently undergoing therapy with VICTRELIS are able to complete up to 48 weeks of treatment, Merck will continue to supply VICTRELIS to wholesalers through December 2015 on an as-needed basis from existing inventories. Remaining inventory is set to expire on December 31, 2015. We recommend that no new patients be initiated on VICTRELIS moving forward.

Please note, as a result of the voluntary product discontinuation, Merck will not have any VICTRELIS with improved product expiry dating beyond that associated with your current inventory and/or upcoming product shipments. Therefore, throughout the year, the product inventory will become increasingly short-dated. As December approaches, your wholesaler may be unable to support a request for the product from their own inventory. If that occurs, please contact your wholesaler to request a drop-shipment of VICTRELIS from Merck.

Indications and Usage

VICTRELIS is indicated for the treatment of chronic hepatitis C virus (HCV) genotype 1 (G1) infection, in combination with peginterferon alfa and ribavirin (PR), in adult patients with compensated liver disease, including cirrhosis, who are previously untreated or who have failed previous interferon and ribavirin therapy, including prior null responders, partial responders, and relapsers.

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 PR.
- The efficacy of VICTRELIS 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.
- Poorly interferon responsive patients who were treated with VICTRELIS in combination with PR 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 PR.

Selected Safety Information

All contraindications to PR also apply since VICTRELIS must be administered with PR. Refer to the respective Prescribing Information for a list of the contraindications for peginterferon and ribavirin.

Because ribavirin may cause birth defects and fetal death, VICTRELIS in combination with PR 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 2 or more forms of effective contraception during treatment and for at least 6 months after treatment has concluded. One of these forms of contraception can be a combined oral contraceptive product containing at least 1 mg of norethindrone. Oral contraceptives containing lower doses of norethindrone and other forms of hormonal contraception have not been studied or are contraindicated.

VICTRELIS is contraindicated in patients with a history of a hypersensitivity reaction to 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 is also contraindicated in coadministration with potent CYP3A4/5 inducers, where significantly reduced VICTRELIS plasma concentrations may be associated with reduced efficacy.

Selected Safety Information *(continued)*

Drugs that are contraindicated with VICTRELIS® (boceprevir) include: alfuzosin, doxazosin, silodosin, tamsulosin, 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 orally administered midazolam.

Anemia and/or Neutropenia – The addition of VICTRELIS to PR is associated with an additional decrease in hemoglobin concentrations compared with PR alone and/or may result in worsening of neutropenia associated with PR therapy alone. Dose reduction or discontinuation of peginterferon alfa and/or ribavirin may be required. If peginterferon alfa or ribavirin is permanently discontinued, VICTRELIS must also be discontinued. Dose reduction of VICTRELIS is not recommended. VICTRELIS must not be administered in the absence of PR.

Serious cases of pancytopenia have been reported postmarketing in patients receiving VICTRELIS in combination with PR.

Complete blood counts (with white blood cell differential counts) should be obtained pretreatment, and at Treatment Weeks 2, 4, 8, and 12, and should be monitored closely at other time points, as clinically appropriate.

Serious acute hypersensitivity reactions (eg, urticaria, angioedema) have been observed during combination therapy with VICTRELIS and PR. If such an acute reaction occurs, combination therapy should be discontinued and appropriate medical therapy immediately instituted.

The most commonly reported adverse reactions (>35%) in clinical trials in adult patients receiving the combination of VICTRELIS with PR were: fatigue, anemia, nausea, headache, and dysgeusia. Of these commonly reported adverse reactions, fatigue, anemia, nausea, and dysgeusia occurred at rates ≥5% above the rates for PR alone in either clinical study. The incidence of these adverse reactions in previously untreated subjects that were treated with combination therapy with VICTRELIS compared with PR alone were: fatigue (58% vs 59%), anemia (50% vs 30%), nausea (46% vs 42%), and dysgeusia (35% vs 16%), respectively. The incidence of these adverse reactions in previous treatment failure patients that were treated with combination therapy with VICTRELIS compared with PR alone were: fatigue (55% vs 50%), anemia (45% vs 20%), nausea (43% vs 38%), and dysgeusia (44% vs 11%), 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 read the accompanying Prescribing Information for VICTRELIS. The Medication Guide also is available.

For more information about Merck products and services, please contact us at the Merck National Service Center at 800-444-2080.

Sincerely,

Paul J. Bader, RPh
Director, Pharmacy & Distribution
Merck Sharp & Dohme Corp.