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var drug_url = "boceprevir-drug";

Boceprevir *(Victrelis)*

Discontinued

Discontinued. This treatment has been discontinued.

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Drug Summary

Boceprevir is a first-generation hepatitis C protease inhibitor that played a valuable role in treatment of patients with genotype 1 infection during the years 2011, 2012, and 2013. With the availability of multiple, new direct-acting antiviral agents that are far superior to boceprevir, Merck has made the decision to discontinue the manufacturing of boceprevir. The relevance of boceprevir is now historical, but prior treatment failure with a boceprevir-based regimen may have resulted in development of resistance-associated variants.

Class and Mechanism

Boceprevir (*Victrelis*) is a NS3/4A protease inhibitor. Specifically, boceprevir inhibits the proteolytic cleavage of the HCV encoded polyprotein, an essential step in the viral life cycle for the production

of mature forms of the viral proteins NS4A, NS4B, NS5A, and NS5B.

Manufacturer for United States

Boceprevir (*Victrelis*) is no longer manufactured in the United States. Boceprevir (*Victrelis*) (Figure 1) was previously manufactured by Merck & Co. Boceprevir was developed at Schering-Plough, which merged with Merck & Co. in 2009.

Cost and Medication Access

Boceprevir (*Victrelis*) is no longer manufactured in the United States.

Adverse Effects

The most common adverse effects reported with boceprevir are anemia, decreased neutrophil count, dysgeusia (alteration in taste), and vomiting. Rare cases of severe hypersensitivity reaction have been reported in patients taking boceprevir in combination with peginterferon and ribavirin. Boceprevir is clasified as pregnancy category B.

Key Drug Interactions

For complete information on boceprevir-related drug interactions, see the Drug Interactions section in the Boceprevir (*Victrelis*) Prescribing Information.

Clinical Trials

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PROVIDE

In this phase 3 trial, which involved 168 patients with genotype 1 chronic hepatitis C who failed prior therapy with peginterferon and ribavirin, investigators retreated these patients with boceprevir plus peginterferon alfa-2b and weight-based ribavirin. The type of treatment failure consisted of prior null response (31%), prior partial response (51%), and prior relapse (17%). All patients received retreatment with a 44-week course of triple therapy consisting of boceprevir, pegintereron-alfa-2b, and ribavirin. In addition, patients who enrolled at least 2 weeks after failing the initial peginterferon and ribavirin treatment course, received a 4-week lead-in treatment with peginteferon alone. Overall, 65% of patients achieved an SVR 24 with retreatment. When examining the retreatment results based on the type of prior failure, the SVR rates varied significantly: prior null response (SVR = 41%), prior partial response (SVR = 67%), and prior relapse (SVR = 96%).

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RESPOND-2

The RESPOND-2 trial examined the impact of boceprevir in treatment-experienced patients with genotype 1 HCV infection. Investigators enrolled 403 patients who previously responded to therapy, but did not achieve an SVR. Investigators randomized patients to one of three treatment arms: (a)

peginterferon plus ribavirin for 48 weeks, (b) boceprevir plus peginterferon plus ribavirin, with response-guided therapy stratification at week 36 to determine final duration of therapy, and (c) fixed duration of therapy with boceprevir plus peginterferon plus ribavirin (44 weeks boceprevir and 48 weeks peginterferon and ribavirin). Patients in the boceprevir arms had higher SVR rates than the patients who received dual therapy. In addition, for patients in the boceprevir arms, better SVR rates were observed in those with prior relapse (SVR 69 to 75%) than those with prior nonresponse (40 to 52%). This study established the benefit of boceprevir added to peginterferon and ribavirin in treatment experienced patients with gentoype 1 HCV infection.

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SPRINT-1

The SPRINT-1 trial was a randomized, open label, phase 2 trial that examined the efficacy of boceprevir in subjects with untreated, genotype 1, chronic hepatitis C infection; less than 10% of the patients enrolled had cirrhosis. The investigators enrolled 520 subjects and the study involved two phases. In part 1, subjects were randomized to one of five treatment arms, including a peginterferon plus ribavirin arm (without boceprevir) and four arms of triple therapy consisting of boceprevir plus peginterferon plus ribavirin (each of these four arms had different treatment courses including two arms with a 4-week peginterferon plus ribavirin lead in). All four of the triple therapy arms performed significantly better than the dual therapy arm (SVR24 54 to 75% with triple therapy arms versus 38% in dual therapy arm). In addition, SVR rates were slightly higher in patients who received a 4-week lead-in with peginterferon and ribavirin. In the second part of the trial, 75 patients received triple therapy with boceprevir plus peginterferon plus ribavirin; the two regimens were the same except that one group received weight-based ribavirin and the other received fixed, low-dose ribavirin. The patients who recieved weight-based ribavirin clearly did better those who received low-dose ribavirin (SVR24 50% versus 36%). Anemia and dysgeusia occurred more frequently in patients who received boceprevir.

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SPRINT-2

In the phase 3 trial, investigators enrolled 1097 treatment-naive patients with genotype 1 chronic HCV and randomized them to receive one of three treatment arms: (a) peginterferon plus ribavirin, (b) boceprevir plus peginterferon plus ribavirin, with response-guided therapy stratification at week 28 to determine final duration of therapy, and (c) fixed duration of therapy with boceprevir plus peginterferon plus ribavirin. In both of the boceprevir regimens, patients received a 4-week lead-in treatment with peginterferon and ribavirin. The SVR rates in the boceprevir triple therapy arms (63 and 66%) were significantly higher than with the dual therapy of peginterferon plus ribavirin (38%). Both nonblack and black patients showed benefit with the addition of boceprevir, but, in each of the three arms, SVR rates were approximately 15% higher in the nonblack patients than black patients.

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Figures

Figure 1 Boceprevir (*Victrelis*) Packaging

Photo: Andrew Karpenko, University of Washington

Figure 2 Boceprevir (*Victrelis*) Capsules

Photo: Andrew Karpenko, University of Washington

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