



VICTRELIS™ (BOCEPREVIR) FACT SHEET

WHAT IS VICTRELIS™?

VICTRELIS™ (boceprevir) is a new oral treatment for chronic hepatitis C (CHC) infection. It is the first in a new class of medicines called hepatitis C virus (HCV) protease inhibitors and is used in combination with the current standard therapy, peginterferon alpha and ribavirin, called peg/riba for simplicity, and available in Canada as either PEGETRON® or PEGASYS®. A direct-acting antiviral, boceprevir attacks the virus itself, versus current standard therapy (peg/riba), which boosts the immune system to elicit a response.

INDICATION

Boceprevir is indicated for the treatment of CHC genotype 1 infection, in combination with peg/riba, in adult patients (18 years and older) with compensated liver disease, including cirrhosis, who are previously untreated (treatment-naïve) or who have failed previous therapy (treatment-failure).¹

PROVEN EFFICACY

Two pivotal studies, SPRINT-2 and RESPOND-2, demonstrated that adding boceprevir to the standard treatment (peginterferon alfa-2b and ribavirin) resulted in a significantly greater number of patients who eliminated the virus, versus standard treatment alone.^{2,3}

A total of 1,500 patients participated in these two clinical trials, with nearly 10 per cent of patients (146) recruited at 15 Canadian investigation sites. In each study, patients were randomized to one of three treatment arms:

- **Response-guided therapy (RGT)**, in which patients commenced treatment with 4 weeks of peginterferon alfa-2b and ribavirin only, followed by the addition of boceprevir. Total treatment duration was based on certain early response criteria. Treatment-failure patients with undetectable virus (HCV-RNA) at weeks 8 and 12 stopped all treatment at 36 weeks.⁴

Treatment-naïve patients who had undetectable virus (HCV-RNA) during weeks 8 through 24 stopped all treatment at 28 weeks.⁵

- **Forty-eight weeks of treatment**, in which patients commenced treatment with 4 weeks of peginterferon alfa-2b and ribavirin only, followed by the addition of boceprevir for another

44 weeks.^{6,7}

- **Control**, in which patients received the standard of care, peginterferon alfa-2b and ribavirin only for 48 weeks.^{8,9}

In the RESPOND-2 study (treatment-failure patients), the addition of boceprevir was shown to eliminate the virus in 66 per cent of patients in the 48-week treatment arm, and in 59 per cent of patients in the RGT arm, compared to 21 per cent in the control group ($p < 0.001$).¹⁰

In the RGT arm, 86 per cent of early responders completed treatment¹¹ – defined as patients with undetectable HCV-RNA at week 8 and week 12 – eliminated the virus and stopped all treatment at

36 weeks, thus shortening therapy by 12 weeks.¹²

In the SPRINT-2 study (naïve patients), the addition of boceprevir was shown to eliminate the virus in 66 per cent of patients in the 48-week treatment arm, and in 63 per cent of patients in the RGT arm, compared to 38 per cent in the control group ($p < 0.001$).¹³ In the RGT arm, 96 per cent of early responders completed treatment¹⁴ – defined as patients with undetectable HCV-RNA at week 8 through week 24¹⁵ – eliminated the virus and stopped all treatment at 28 weeks, thus shortening therapy by 20 weeks.¹⁶

TOLERABILITY PROFILE

In treatment-failure patients

The five most common treatment-related adverse events in the RESPOND-2 study, reported for patients in each of the three study arms – boceprevir in RGT, boceprevir in a 48-week treatment regimen and control – were fatigue, headache, nausea, anemia and chills. Serious adverse events were reported in 10, 14 and five per cent of patients in the respective study arms.

In treatment-naïve patients

The five most common treatment-related adverse events in the SPRINT-2 study reported for patients in each of the three study arms – boceprevir in RGT, boceprevir in a 48-week treatment regimen and control – were fatigue, headache, nausea, anemia and dysgeusia (bad taste). Serious adverse events were reported in 11, 12 and nine per cent of patients in the respective study arms.

In both studies, discontinuation rates due to adverse events were 13 per cent in the boceprevir arms and 12 per cent for the control arms.

DOSAGE

The recommended dose of boceprevir is 800 mg (four 200 mg capsules) taken orally three times a day (every seven to nine hours) with food (a meal or light snack).

Boceprevir should not be used as a single treatment but only in combination with peg/riba.

AVAILABILITY

VICTRELIS™ (boceprevir) is now available in Canada. The cost depends on the length of treatment.

The list price is \$1,050.00 per week.

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PEGASYS® is a registered trademark of F. Hoffmann-La Roche AG.

References:

- 1 VICTRELIS™, Product Monograph, July 27, 2011, page 3.
- 2 Poordad, F., et al., for the SPRINT-2 Investigators. Boceprevir for Untreated Chronic HCV Genotype 1 Infection. *N Engl J Med* 2011; 364:1195-1206, page 1195.
- 3 Bacon, B.R., et al., for the HCV RESPOND-2 Investigators. Boceprevir for Previously Treated Chronic HCV Genotype 1 Infection. *N Engl J Med* 2011; 364:1207-1217, page 1207.
- 4 Ibid, page 1209.
- 5 Poordad, F., et al., for the SPRINT-2 Investigators. Boceprevir for Untreated Chronic HCV Genotype 1 Infection. *N Engl J Med* 2011; 364:1195-1206. Page 1197.
- 6 Ibid, page 1197.
- 7 Bacon, B.R., et al., for the HCV RESPOND-2 Investigators. Boceprevir for Previously Treated Chronic HCV Genotype 1 Infection. *N Engl J Med* 2011; 364:1207-1217, page 1207.
- 8 Ibid.
- 9 Poordad, F., et al., for the SPRINT-2 Investigators. Boceprevir for Untreated Chronic HCV Genotype 1 Infection. *N Engl J Med* 2011; 364:1195-1206, page 1197.
- 10 Bacon, B.R., et al., for the HCV RESPOND-2 Investigators. Boceprevir for Previously Treated Chronic HCV Genotype 1 Infection. *N Engl J Med* 2011; 364:1207-1217, page 1207.
- 11 Ibid.
- 12 Ibid, page 1209.
- 13 Poordad, F., et al., for the SPRINT-2 Investigators. Boceprevir for Untreated Chronic HCV Genotype 1 Infection. *N Engl J Med* 2011; 364:1195-1206, page 1200-1201.
- 14 Ibid, page 1201.
- 15 Ibid, page 1200.
- 16 Ibid, page 1197.