Boceprevir Shows Promise for Previously Treated and Newly Treated Hep C

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"The most difficult aspect of managing hepatitis C is that treatment is an extremely long process that is often debilitating for many patients," said Stephen Shafran, MD, FRCPC, FACP, of the University of Alberta and an investigator in the SPRINT-2 trial. "These results are extremely exciting because boceprevir substantially increased success rates compared to standard therapy and many of the patients were able to be treated for 28 to 36 weeks."

The RESPOND-2 and SPRINT-2 studies each evaluated two treatment strategies to assess whether adding boceprevir to pegylated interferon and ribavirin could improve SVR rates and potentially shorten overall treatment duration compared with using pegylated interferon/ribavirin alone for 48 weeks, which is the current standard duration of therapy.

In each study, patients were randomized to three groups. In the first group, study subjects underwent response-guided therapy (RGT), in which total treatment duration was based on certain early response criteria. Patients in RESPOND-2 with undetectable HCV viral loads at week 8 were eligible to stop all treatment at 36 weeks. Patients in SPRINT-2 with undetectable virus during weeks 8 through 24 were eligible to stop all treatment at 28 weeks. In the second group, all patients received 48 weeks of treatment, starting with pegylated interferon/ribavirin alone then adding boceprevir after 4 weeks. In the third group—the control arm—patients received standard pegylated interferon/ribavirin, without boceprevir, for 48 weeks.

RESPOND-2 enrolled 403 adult patients who had failed prior therapy, including patients who relapsed or were non-responders to prior treatment with pegylated interferon/ribavirin. SPRINT-2 enrolled 1,097 first-time HCV treatment takers enrolled in two separate cohorts, one with 938 non-black patients and the other with 159 black patients.

As Merck previously reported, boceprevir in RESPOND-2 increased SVR rates to 59 percent in the RGT group and 66 percent in the 48-week treatment arm, compared with 21 percent in the control arm. In SPRINT-2, boceprevir increased SVR rates to 63 percent for the RGT group and 66 percent in the 48-week treatment arm, compared with 38 percent in the control arm. These differences were statistically significant, meaning that they were too great to have occurred by chance.

According to new data reported at AASLD, nearly half the patients in the boceprevir RGT groups met early response criteria and, in turn, were allowed to discontinue treatment early. In the RGT

group of RESPOND-2, 46 percent of the patients met the early response criteria and were eligible to stop all treatment at 36 weeks, which is 12 weeks shorter than current standard therapy. In these patients, the SVR rate was 86 percent. In the RGT group of SPRINT-2, 44 percent of patients met the early response criteria and were eligible to stop all treatment at 28 weeks, which is 20 weeks shorter than current standard therapy. In these patients, the SVR rates were 97 percent in non-black treatment-naive patients and 87 percent (13/15) in black treatment-naive patients. For the corresponding patients in the boceprevir 48-week treatment arms of these studies, the SVR rates were 88 percent in RESPOND-2, 96 percent among non-black SPRINT-2 study volunteers and 95 percent in black SPRINT-2 study volunteers.

Patients in the boceprevir RGT arms of these studies who did not meet the early response criteria and were treated for up to 48 weeks also achieved substantially higher SVR rates compared with the control. In these patients, the SVR rates were 40 percent in RESPOND-2, 74 percent in non-black SPRINT-2 volunteers and 58 percent in black SPRINT-2 volunteers.

The five most common treatment-related adverse events among patients who received boceprevir in RESPOND-2 were fatigue, headache, nausea, chills and flu-like illness. Anemia and bad taste was also documented.

Treatment discontinuations in RESPOND-2 due to adverse events over the total course of all treatment were 8 percent and 12 percent for the boceprevir RGT and 48-week treatment arms, respectively, compared with 3 percent in the control arm. Treatment discontinuations in SPRINT-2 due to adverse events were 12 percent and 16 percent for the boceprevir RGT and 48-week treatment arms, respectively, compared with 16 percent for the control.

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