**Poster LB16**

**Boceprevir Plus Peginterferon alfa-2b/Ribavirin for Treatment of Genotype 1 Chronic Hepatitis C in Previously Untreated Patients: Interim Results from the HCV SPRINT-1 Study**

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**Abstract**

Background: Boceprevir (Boc) is an HCV NS3 protease inhibitor being assessed in combination with peginterferon alfa-2b (P) 1.5 µg/kg and ribavirin (R) for chronic hepatitis C.

Methods: HCV SPRINT-1 is a Phase 2 study in HCV patients evaluating Boc 800 mg or 1200 mg in three treatment regimens: 1) 4 weeks of P/R 1800-1400 mg/d (lead-in) followed by 8 weeks of Boc for 24 weeks (total 28 in 48 weeks); 2) Boc in combination with P/R (800-1400 mg/d) for 28 or 48 weeks; 3) 28 weeks of P/R/B (1.5 µg/kg, 1800-1400 mg/d) followed by 20 weeks of Boc (28 total 48 weeks).

Results: 111 patients (P/R/B 80; Boc 800 mg 24; Boc 1200 mg 28) were randomized to the three arms. Baseline characteristics were comparable. An interim analysis was performed at 48 weeks.

Conclusions: The addition of boceprevir markedly increased SVR with 28- and 48-week regimens compared with P/R control. SVR 24 for 28-week arms

**Background**

- PegIntron, ribavirin (800 to 1400 mg/d), and boceprevir for 48 weeks (Arm 6)
- PegIntron, ribavirin, and boceprevir for 28 weeks (Arm 2)

**Methods**

- This is an open-label randomized trial conducted in two parts
- Part 1 has 5 treatment arms, randomized 1:1:1:1:1, and compares PegIntron and ribavirin for 4 weeks followed by PegIntron, ribavirin, and boceprevir for 44 weeks (Arm 5)
- PegIntron, ribavirin, and boceprevir for 48 weeks (Arm 4)
- PegIntron and ribavirin for 4 weeks followed by PegIntron, ribavirin, and boceprevir for 24 weeks (Arm 3)
- PegIntron, ribavirin, and boceprevir for 28 weeks (Arm 2)
- PegIntron and ribavirin for 48 weeks (Control Arm 1)

**Aims**

- Evaluate the safety and efficacy of boceprevir in combination with PegIntron 1.5 µg/kg and ribavirin in previously untreated adults with genotype 1 chronic hepatitis C.
- Assess the effect of 4-week lead-in with PegIntron and ribavirin on SVR
- Assess the duration of treatment with boceprevir required to reduce viral breakthrough in patients treated with PegIntron/Ribavirin for 4-12 weeks

**Results**

**Table 1. Baseline Characteristics**

<table>
<thead>
<tr>
<th>Treatment Arm</th>
<th>Male (%)</th>
<th>Race</th>
<th>HCV Subtype (%)</th>
<th>BMI (kg/m²)</th>
<th>HCV-RNA at 4 weeks (IU/mL)</th>
<th>HCV-RNA at 12 weeks (IU/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>P/R-B</td>
<td>92</td>
<td>67</td>
<td>genotype 1</td>
<td>28.0</td>
<td>74 (32/43)</td>
<td>6.6 (48/79)</td>
</tr>
<tr>
<td>Boc 800 mg</td>
<td>92</td>
<td>67</td>
<td>genotype 1</td>
<td>28.0</td>
<td>74 (32/43)</td>
<td>6.6 (48/79)</td>
</tr>
<tr>
<td>Boc 1200 mg</td>
<td>92</td>
<td>67</td>
<td>genotype 1</td>
<td>28.0</td>
<td>74 (32/43)</td>
<td>6.6 (48/79)</td>
</tr>
</tbody>
</table>

**Figure 1. Part 1 Study Design**

- **Lead-in Strategy:**
  - Boc 800 mg for 4 weeks
  - Boc 1200 mg for 4 weeks

- **No Lead-in Strategy:**
  - Boc 800 mg for 24 weeks
  - Boc 1200 mg for 24 weeks

**Figure 2. Sustained Virologic Response**

- SVR defined as undetectable HCV-RNA at week 24.

**Figure 3. Predictability of Attaining SVR 12 or 24 Based on RVR**

**Figure 4. Predictability of Attaining SVR 12 or 24 Based on ETV**

**Table 2. Common Adverse Events**

<table>
<thead>
<tr>
<th>Event</th>
<th>Boc 1200 mg</th>
<th>Boc 800 mg</th>
<th>P/R-B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Malignancies (%)</td>
<td>3.6 (3.6%)</td>
<td>0 (0%)</td>
<td>3.0 (2.9%)</td>
</tr>
<tr>
<td>Diarrhea (%)</td>
<td>23.9 (23.9%)</td>
<td>22.6 (22.6%)</td>
<td>25.8 (25.8%)</td>
</tr>
<tr>
<td>Fatigue (%)</td>
<td>11.5 (11.5%)</td>
<td>11.5 (11.5%)</td>
<td>9.0 (9.0%)</td>
</tr>
<tr>
<td>AST (IU/L)</td>
<td>38</td>
<td>48</td>
<td>48</td>
</tr>
<tr>
<td>Bilirubin (mg/dL)</td>
<td>0.2</td>
<td>0.2</td>
<td>0.2</td>
</tr>
<tr>
<td>Creatinine (mg/dL)</td>
<td>0.9</td>
<td>0.9</td>
<td>0.9</td>
</tr>
<tr>
<td>Haemoglobin (g/dL)</td>
<td>14.5</td>
<td>14.5</td>
<td>14.5</td>
</tr>
<tr>
<td>Hgb (g/dL)</td>
<td>14.5</td>
<td>14.5</td>
<td>14.5</td>
</tr>
<tr>
<td>Hct (%)</td>
<td>43.4</td>
<td>43.4</td>
<td>43.4</td>
</tr>
<tr>
<td>Platelets (x 10^12/L)</td>
<td>239</td>
<td>239</td>
<td>239</td>
</tr>
<tr>
<td>WBC (x 10^9/L)</td>
<td>7.1</td>
<td>7.1</td>
<td>7.1</td>
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</tbody>
</table>

**References**


**Disclosures**

- No proprietary interests.
- No financial interests.
- No relationships with industry or any other institution.

**Summary**

- In this study, boceprevir when combined with P/R is safe for use up to 48 weeks and substantially improves SVR rates with 28 weeks of therapy and cure nearly doubly the proportion of genotype 1 patients treated with P/R.

Presented at the 59th Annual Meeting of the American Association for the Study of Liver Diseases; October 31 – November 4, 2008; San Francisco, California