Boceprevir in Treatment Naive
SPRINT-2
Boceprevir for Treatment-Naïve HCV Genotype 1
SPRINT-2 Trial: Study Design

**SPRINT-2: Study Features**
- N = 1097 HCV-monoinfected patients (159 black)
- Randomized, double-blind, placebo-controlled, phase 3 study
- All with chronic HCV and genotype 1 and treatment naïve
- HCV RNA ≥ 10,000 IU/ml
- Age ≥ 18
- Setting: international sites
- Randomized to 3 arms (1:1:1)

**Drug Dosing**
- Boceprevir = 800 mg three times daily
- Peginterferon alfa-2b = 1.5 μg/kg once weekly
- Ribavirin = 600-1400 mg/day (based on weight)

Boceprevir for Treatment-Naïve HCV Genotype 1
SPRINT-2 Trial: Treatment Regimens

<table>
<thead>
<tr>
<th>Week</th>
<th>0</th>
<th>4</th>
<th>12</th>
<th>24</th>
<th>28</th>
<th>48</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead In</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>✓</td>
<td>HCV RNA</td>
<td></td>
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</tr>
</tbody>
</table>

PR48

- **Peginterferon + Ribavirin**

B24

- **Boceprevir**

PR28-48

- **Peginterferon + Ribavirin**

<table>
<thead>
<tr>
<th>Week</th>
<th>8-24</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Stop Therapy</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Week</th>
<th>8-24</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Detectable HCV RNA</td>
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Boceprevir for Treatment-Naïve HCV Genotype 1

SPRINT-2 Trial: Treatment Regimens

SPRINT-2: SVR 24 by Regimen

Patients with SVR (%)

PR48

B24/PR28-48

B44/PR48

B = Boceprevir; PR = Peginterferon + Ribavirin

Boceprevir for Treatment-Naïve HCV Genotype 1
SPRINT-2 Trial: Results

SPRINT-2: SVR 24 by Regimen

<table>
<thead>
<tr>
<th>Regimen</th>
<th>All</th>
<th>Black</th>
<th>Nonblack</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>137/163</td>
<td>12/52</td>
<td>125/311</td>
</tr>
<tr>
<td>PR48</td>
<td>233/368</td>
<td>22/52</td>
<td>211/316</td>
</tr>
<tr>
<td>B24/PR28-48</td>
<td>242/366</td>
<td>29/55</td>
<td>213/311</td>
</tr>
<tr>
<td>B44/PR48</td>
<td>63</td>
<td>66</td>
<td>67</td>
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</tbody>
</table>

Patients with SVR (%)

SVR = Sustained Virologic Response; B = Boceprevir; PR = Peginterferon + Ribavirin

Boceprevir for Treatment-Naïve HCV Genotype 1
SPRINT-2 Trial: SVR by Liver Histology

SPRINT-2: SVR 24 by Degree of Fibrosis

PR48 = Peginteron/Ribavirin x 48 weeks
SVR = Sustained Virologic Response; B = Boceprevir; PR = Peginterferon + Ribavirin

**Conclusions:** “The addition of boceprevir to standard therapy with peginterferon–ribavirin, as compared with standard therapy alone, significantly increased the rates of sustained virologic response in previously untreated adults with chronic HCV genotype 1 infection. The rates were similar with 24 weeks and 44 weeks of boceprevir.”