Telaprevir in Treatment Naïve GT-1
ILLUMINATE (Study 111)

**Telaprevir for Treatment-Naïve HCV Genotype 1**

**ILLUMINATE: Study Design**

**ILLUMINATE: Study Features**
- Randomized, open label, Phase 3 trial
- Genotype 1 HCV and treatment naïve, with or without cirrhosis
- N = 540 enrolled
- RVR = HCV RNA undetectable at week 4
- eRVR = HCV RNA undetectable at weeks 4 & 12
- Erythroid stimulating agents not allowed
- All received telaprevir x 12 weeks
- Patients with eRVR randomized to PR for 24 or 48 weeks
- Patients without eRVR received PR x 48 weeks

**Drug Dosing**
Telaprevir = 750 mg every 8 hours
Peginterferon alfa-2a = 180 μg per week
Ribavirin = 1000 mg/day for wt < 75 kg; 1200 mg/day for wt ≥ 75 kg

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ILLUMINATE Study: Design

Week 0 12 20 24 48

With eRVR

PR

Telaprevir

PEG + Ribavirin (PR)

Without eRVR

PR

eRVR (+) T12/PR24

T12 PR 24 or 48

PR

eRVR (+) T12/PR48

eRVR (-) T12/PR48

T = Telaprevir
PR = Peginterferon + Ribavirin
eRVR = extended rapid virologic response (undetectable HCV RNA at weeks 4 and 12)

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ILLUMINATE Study: Results

ILLUMINATE: SVR 24 by Regimen

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Patients with SVR (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>72/540</td>
</tr>
<tr>
<td>eRVR (+)</td>
<td>92/162</td>
</tr>
<tr>
<td>eRVR (+)</td>
<td>88/160</td>
</tr>
<tr>
<td>eRVR (-)</td>
<td>64/118</td>
</tr>
</tbody>
</table>

Patients with SVR (%)

SVR = Sustained virologic response; T = Telaprevir; PR = Peginterferon + Ribavirin
eRVR = extended rapid virologic response (undetectable HCV RNA at weeks 4 and 12)

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ILLUMINATE Study: Key Findings

- 24 weeks of Peg-IFN non-inferior to 48 weeks in patients with eRVR
- Overall SVR 72%
- SVR in 60% of blacks
- SVR of 63% in patients with cirrhosis
- 65% of patients had eRVR
- 88-92% of those who achieved eRVR achieved SVR
- 7% stopped treatment early due to virologic failure
- 17% stopped early due to fatigue or anemia

Conclusions: “In this study, among patients with chronic HCV infection who had not received treatment previously, a regimen of peginterferon–ribavirin for 24 weeks, with telaprevir for the first 12 weeks, was noninferior to the same regimen for 48 weeks in patients with undetectable HCV RNA at weeks 4 and 12, with an extended rapid virologic response achieved in nearly two thirds of patients.”