Telaprevir in Treatment Experienced GT-1
REALIZE (Study 216)

# Telaprevir for Treatment-Experienced HCV Genotype 1

## REALIZE Study: Study Design

### REALIZE: Study Features

- Phase 3 trial
- Randomized, double-blind, placebo-controlled
- Eligible if 18 to 70 years of age
- All with genotype 1 chronic HCV infection
- Lack of SVR with prior peginterferon + ribavirin treatment
- N = 663 enrolled
- Setting: 100 international sites (most in Europe and US)
- Randomized to one of 3 arms (2:2:1 ratio)

### Drug Dosing

- Telaprevir = 750 mg q8h
- Peginterferon alfa-2a = 180 µg weekly
- Ribavirin = 1000 mg/day for wt < 75 kg; 1200 mg/day for wt ≥ 75 kg

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REALIZE Study: Definitions for Prior Response

- **No Response**: Reduction of less than $2 \log_{10}$ in HCV RNA after 12 weeks of therapy

- **Partial Response**: Reduction of $2 \log_{10}$ or more in HCV RNA after 12 weeks of therapy, but with detectable HCV RNA

- **Relapse**: undetectable HCV RNA at the end of a previous course of therapy but HCV RNA positivity thereafter

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REALIZE Study: Results

REALIZE: SVR24 by Regimen

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Patients with SVR (%)</th>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>T12/PR48 (no lead in)</td>
<td>64/171</td>
<td>266/171</td>
</tr>
<tr>
<td>T12/PR48 (with lead in)</td>
<td>66/175</td>
<td>264/175</td>
</tr>
<tr>
<td>PR48</td>
<td>17/22</td>
<td>132/22</td>
</tr>
</tbody>
</table>

SVR = Sustained Virologic Response; T = Telaprevir, PR = Peginterferon + Ribavirin

Telaprevir for Treatment-Experienced HCV Genotype 1
REALIZE: Results Based on Prior History

REALIZE: SVR24 by Prior Response

<table>
<thead>
<tr>
<th>Previous Type of Response</th>
<th>T12/PR48 (no lead in)</th>
<th>T12/PR48 (with lead in)</th>
<th>PR 48</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Response</td>
<td>21/72</td>
<td>25/75</td>
<td>2/37</td>
</tr>
<tr>
<td>Partial Response</td>
<td>29/49</td>
<td>26/48</td>
<td>4/27</td>
</tr>
<tr>
<td>Relapse</td>
<td>121/145</td>
<td>124/141</td>
<td>16/68</td>
</tr>
</tbody>
</table>

SVR = Sustained Virologic Response; T = Telaprevir; PR = Peginterferon + Ribavirin

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REALIZE: Adverse Effects

REALIZE: Anemia

Hemoglobin (Hb) Nadir Through Week 12

- Hb 8.5 to ≤10 g/dL
  - T12/PR48 (no lead in): 71/266
  - T12/PR48 (with lead in): 73/264
  - PR48: 20/132

- Hb < 8.5 g/dL
  - T12/PR48 (no lead in): 28/266
  - T12/PR48 (with lead in): 36/264
  - PR48: 11/132

T = Telaprevir; P = Peginterferon + Ribavirin

**Conclusions:** “Telaprevir combined with peginterferon plus ribavirin significantly improved rates of sustained virologic response in patients with previously treated HCV infection, regardless of whether there was a lead-in phase.”