Elbasvir-Grazoprevir +/- Ribavirin in HCV Genotype 1, 4 or 6
C-EDGE Treatment Experienced (TE)

Elbasvir-Grazoprevir +/- Ribavirin in HCV Genotype 1, 4 or 6
C-EDGE TE Study: Features

C-EDGE TE Trial

- **Design**: Randomized, open label, parallel-group, phase 3 trial examining the safety and efficacy of a fixed-dose combination of elbasvir-grazoprevir with or without ribavirin for 12 or 16 weeks in treatment-experienced adults with GT 1, 4, or 6 HCV and previous failure of peginterferon plus ribavirin.

- **Entry Criteria**
  - Chronic HCV Genotype 1, 4 or 6
  - 18 years or older
  - HCV RNA ≥10,000 IU/mL
  - History of peginterferon plus ribavirin treatment failure
  - Patients with compensated cirrhosis accepted
  - Some patients with HIV infection accepted

- **Primary End-Point**: SVR12

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C-EDGE TE: Study Design

### Abbreviations
- **EBR-GZR** = elbasvir-grazoprevir
- **RBV** = ribavirin

### Drug Dosing
- **Elbasvir-grazoprevir (50/100 mg)**: fixed dose combination; one pill once daily
- **Ribavirin (weight-based and divided bid)**: 800 to 1400 mg/day

Elbasvir-Grazoprevir +/- Ribavirin in HCV Genotype 1, 4 or 6 C-EDGE TE: Baseline Characteristics

<table>
<thead>
<tr>
<th>Baseline Characteristic</th>
<th>12-Week Treatment</th>
<th>16-Week Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EBR-GRZ (n = 105)</td>
<td>EBR-GRZ + RBV (n = 104)</td>
</tr>
<tr>
<td>Age, yrs median (range)</td>
<td>56 (25–76)</td>
<td>56 (23–75)</td>
</tr>
<tr>
<td>Male sex, %</td>
<td>63</td>
<td>69</td>
</tr>
<tr>
<td>Race, n (%):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>66 (63)</td>
<td>70 (67)</td>
</tr>
<tr>
<td>African American</td>
<td>23 (22)</td>
<td>24 (23)</td>
</tr>
<tr>
<td>Asian</td>
<td>15 (14)</td>
<td>9 (9)</td>
</tr>
<tr>
<td>HCV Genotype, %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1a</td>
<td>61 (58)</td>
<td>60 (58)</td>
</tr>
<tr>
<td>1b</td>
<td>34 (32)</td>
<td>29 (28)</td>
</tr>
<tr>
<td>4</td>
<td>9 (9)</td>
<td>15 (14)</td>
</tr>
<tr>
<td>6</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Cirrhosis, %</td>
<td>37 (35)</td>
<td>35 (34)</td>
</tr>
<tr>
<td>HIV coinfection, %</td>
<td>6 (6)</td>
<td>5 (5)</td>
</tr>
<tr>
<td>Prior treatment response</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relapse, %</td>
<td>35 (33)</td>
<td>38 (37)</td>
</tr>
<tr>
<td>Partial response, %</td>
<td>21 (20)</td>
<td>22 (21)</td>
</tr>
<tr>
<td>Prior null, %</td>
<td>49 (47)</td>
<td>44 (42)</td>
</tr>
</tbody>
</table>

Elbasvir-Grazoprevir +/- Ribavirin in HCV Genotype 1, 4 or 6

C-EDGE TE: Results

C-EDGE TE: SVR 12*, by Genotype

* Analysis per protocol: excluding patients who dropped out due to reasons other than virologic failure

Elbasvir-Grazoprevir +/- Ribavirin in HCV Genotype 1, 4 or 6

C-EDGE TE: Results

C-EDGE TE: SVR 12* by Regimen and Treatment Duration (GT 1, 4, or 6)

* Analysis per intent to treat

Elbasvir-Grazoprevir +/- Ribavirin in HCV Genotype 1, 4 or 6

C-EDGE TE: Results

C-EDGE TE: SVR 12 by Regimen, Treatment Duration, and GT1 Subtype

![Bar chart showing SVR 12 by regimen, treatment duration, and GT1 subtype]

Elbasvir-Grazoprevir +/- Ribavirin in HCV Genotype 1, 4 or 6

C-EDGE TE: Results

C-EDGE TE: SVR 12 in Patients with Baseline NS5A RAVs

Elbasvir-Grazoprevir +/- Ribavirin in HCV Genotype 1, 4 or 6 C-EDGE TE: Results

Conclusions: “The combination tablet of elbasvir and grazoprevir, with or without ribavirin, was highly efficacious in inducing an SVR12 in patients with HCV genotype 1, 4, or 6 infection failed by previous treatment with peg-interferon and ribavirin, including patients with cirrhosis and/or a prior null response. The treatment was generally well tolerated.”