Elbasvir-Grazoprevir + Sofosbuvir in Treatment-Naïve HCV Genotype 1 or 3

C-SWIFT

Elbasvir-Grazoprevir + Sofosbuvir in Treatment-Naïve GT 1 or 3
C-SWIFT Study: Features

**C-SWIFT Trial**

- **Design:** Open-label phase 2 trial to evaluate the efficacy and safety of short duration therapy with elbasvir-grazoprevir + sofosbuvir in treatment-naïve GT 1 or 3 infection, with or without cirrhosis

- **Entry Criteria**
  - Chronic HCV Genotype 1 (n=102) or Genotype 3 (n=41)
  - 18 years or older
  - No prior HCV treatment
  - HCV RNA ≥10,000 IU/ml
  - ALT and AST <350 IU/L
  - Cirrhosis allowed

- **Primary End-Point:** SVR12
Elbasvir-Grazoprevir + Sofosbuvir in Treatment-Naïve GT 1 or 3 C-SWIFT Study: Study Design for GT 1

**Abbreviations:** EBR-GZR = elbasvir-grazoprevir; SOF = sofosbuvir

**Drug Dosing**
Elbasvir-grazoprevir (50/100 mg): fixed-dose combination; one pill once daily
Sofosbuvir: 400 mg once daily

**Source:** Poordad F, et al. EASL 2015; Abstract O006.
Elbasvir-Grazoprevir + Sofosbuvir in Treatment-Naïve GT 1 or 3
C-SWIFT Study: Study Design for GT 3

**Source:** Poordad F, et al. EASL 2015; Abstract O006.

### Abbreviations:
- EBR-GZR = grazoprevir-elbasvir
- SOF = sofosbuvir

### Drug Dosing
Grazoprevir/elbasvir (100/50 mg): fixed dose combination; one pill once daily
Sofosbuvir 400 mg once daily
Elbasvir-Grazoprevir + Sofosbuvir in Treatment-Naïve GT 1 or 3 C-SWIFT Study: Baseline Characteristics

<table>
<thead>
<tr>
<th>Baseline Characteristic</th>
<th>Genotype 1</th>
<th>Genotype 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No cirrhosis</td>
<td>Cirrhosis</td>
</tr>
<tr>
<td></td>
<td>4 weeks N=31</td>
<td>6 weeks N=30</td>
</tr>
<tr>
<td>Mean age, years</td>
<td>52</td>
<td>51</td>
</tr>
<tr>
<td>Male sex, %</td>
<td>65</td>
<td>63</td>
</tr>
<tr>
<td>Race, %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>97</td>
<td>93</td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>29</td>
<td>47</td>
</tr>
<tr>
<td>HCV Genotype, %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1a</td>
<td>84</td>
<td>87</td>
</tr>
<tr>
<td>1b</td>
<td>16</td>
<td>13</td>
</tr>
<tr>
<td>3</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>IL28B CC, %</td>
<td>36</td>
<td>27</td>
</tr>
<tr>
<td>Cirrhosis, %</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>HCV RNA, 10^6 IU/ml (mean)</td>
<td>3.7</td>
<td>3.1</td>
</tr>
</tbody>
</table>

Elbasvir-Grazoprevir + Sofosbuvir in Treatment-Naïve GT 1 or 3
C-SWIFT Study: Results for GT 1

C-SWIFT: SVR 12* for GT 1 by Treatment Duration and Cirrhosis

*Analysis by modified intention-to-treat analysis (excluded patients who discontinued due to reasons other than virologic failure)

Elbasvir-Grazoprevir + Sofosbuvir in Treatment- naïve GT 1 or 3

C-SWIFT Study: Results for GT 3

C-SWIFT: SVR 12* for GT 3 by Treatment Duration and Cirrhosis

Analysis by modified intention-to-treat analysis (excluded patients who discontinued due to reasons other than virologic failure)

Elbasvir-Grazoprevir + Sofosbuvir in Treatment-Naïve GT 1 or 3 C-SWIFT Study: Conclusions

**Conclusions:** “A novel regimen of grazoprevir/elbasvir with sofosbuvir was able to shorten treatment duration to 8 weeks or less among cirrhotic and non-cirrhotic HCV genotype 1-infected patients.”

“Genotype 3 patients achieved high SVR12 rates with 8-12 weeks of therapy, including patients with cirrhosis.”