Retreatment of Sofosbuvir + Ribavirin Failure with Sofosbuvir-Containing Regimens in Patients with Genotype 2 or 3

Retreatment of Sofosbuvir + Ribavirin Failure: Features

- **Design**: Open-label, study for patients with GT 2 or 3 who had failure with sofosbuvir + ribavirin in FISSION, POSITRON, or FUSION trial

- **Setting**: Europe, United States, and Canada

- **Entry Criteria**
  - N = 107 patients with chronic HCV
  - HCV genotype 2 (10%) or HCV genotype 3 (90%)
  - Previous relapse on sofosbuvir plus ribavirin
  - Patients with compensated cirrhosis allowed to enroll

- **Regimens (patients offered 2 possible regimens)**
  - Sofosbuvir + Ribavirin x 24 weeks
  - Sofosbuvir + Peginterferon + Ribavirin x 12 weeks

- **Primary End-Point**: SVR12

Retreatment of SOF + RBV Failure with SOF-Containing Regimens in GT 2 or 3

Baseline Characteristics

<table>
<thead>
<tr>
<th>Baseline Characteristic</th>
<th>SOF + PEG + RBV x 12 weeks (n = 34)</th>
<th>SOF + RBV x 24 weeks (n = 73)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (range)</td>
<td>53 (31-70)</td>
<td>53 (38-63)</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>26 (77%)</td>
<td>63 (86%)</td>
</tr>
<tr>
<td>White, n (%)</td>
<td>1 (1%)</td>
<td>0</td>
</tr>
<tr>
<td>Mean BMI kg/m² (range)</td>
<td>29 (22-39)</td>
<td>28 (20-41)</td>
</tr>
<tr>
<td>Cirrhosis, %</td>
<td>14 (41%)</td>
<td>25 (34%)</td>
</tr>
<tr>
<td>IL28B CC, n (%)</td>
<td>11 (32%)</td>
<td>27 (37%)</td>
</tr>
<tr>
<td>Genotype, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>6 (18%)</td>
<td>5 (7%)</td>
</tr>
<tr>
<td>3</td>
<td>28 (82%)</td>
<td>68 (93%)</td>
</tr>
<tr>
<td>Mean baseline HCV RNA, log₁₀ IU/ml (range)</td>
<td>6.3 (4.8-7.8)</td>
<td>6.6 (4.4-7.6)</td>
</tr>
</tbody>
</table>
Retreatment of SOF + RBV Failure with SOF-Containing Regimens in GT 2 or 3

**Study Design**

- **GT2 or GT3**
  - **N = 73**
  - **Sofosbuvir + RBV**

- **GT2 or GT3**
  - **N = 34**
  - **Sofosbuvir + PEG + RBV**

**Drug Dosing**

- Sofosbuvir: 400 mg once daily
- Peginterferon alfa-2a: 180 µg once weekly
- Weight-based Ribavirin (in 2 divided doses): 1000 mg/day if < 75 kg or 1200 mg/day if ≥ 75 kg

**Source:** Esteban R, et al. 49th EASL; April 2014. Abstract 08.
Retreatment of SOF + RBV Failure with SOF-Containing Regimens in GT 2 or 3

Results, by Genotype

SVR12 by Regimen and HCV Genotype

Retreatment of SOF + RBV Failure with SOF-Containing Regimens in GT 2 or 3

Results, by Genotype

SVR12 by Regimen and HCV Genotype

<table>
<thead>
<tr>
<th>Genotype 2</th>
<th>Genotype 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOF + PEG + RBV x 12 wks</td>
<td>SOF + RBV x 24 wks</td>
</tr>
<tr>
<td>4/4</td>
<td>20/22</td>
</tr>
<tr>
<td>1/2</td>
<td>24/38</td>
</tr>
</tbody>
</table>

Patients (%) with SVR12

This slide deck is from the University of Washington’s Hepatitis C Online and Hepatitis Web Study projects.

Hepatitis C Online
www.hepatitisc.uw.edu

Hepatitis Web Study
http://depts.washington.edu/hepstudy/

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