Sofosbuvir in Genotype 2 or 3
FUSION Trial

*Note: Published in NEJM in tandem with POSITRON Trial (GT 2,3 Unable to receive PEG)

Sofosbuvir + RBV in Treatment-Experienced HCV GT 2 or 3

**FUSION Trial: Features**

- **Design**: Randomized, controlled, blinded phase 3 trial comparing 12 and 16 weeks of sofosbuvir + ribavirin in treatment-experienced HCV GT 2 or 3
- **Setting**: 67 sites in US, Canada, New Zealand, enrolled May-July 2012
- **Entry Criteria**
  - Treatment-experienced (failed prior interferon-based therapy)
  - HCV RNA ≥ 10,000 IU/ml
- **Patient Characteristics**
  - N = 201 HCV-monoinfected patients
  - HCV genotype: 2 (34%); 3 (63%)
  - IL28B genotype: 70% non-CC
  - Prior treatment failure: 75% relapse; 25% nonresponse
  - Age and sex: mean age 54 (range 24-70); 70% male
  - Race: 87% white; 3% black
  - Liver disease: 34% had cirrhosis
- **Primary End-Point**: SVR12

# Sofosbuvir + RBV in Treatment-Experienced HCV GT 2 or 3 FUSION Trial: Design

## Drug Dosing
- **Sofosbuvir**: 400 mg once daily
- **Weight-Based Ribavirin (in 2 divided doses)**: 1000 mg/day if < 75 kg or 1200 mg/day if ≥ 75 kg

## Week 0-28 Timeline

<table>
<thead>
<tr>
<th>Week</th>
<th>Sofosbuvir + RBV 12 weeks</th>
<th>Sofosbuvir + RBV 16 weeks</th>
<th>Placebo</th>
<th>SVR12</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 103</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N = 98</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
Sofosbuvir + RBV in Treatment-Experienced HCV GT 2 or 3 FUSION Trial: Results

FUSION: HCV RNA <25 IU/ml by Study Timepoint

<table>
<thead>
<tr>
<th>Timepoint</th>
<th>SOF + RBV (12 wk)</th>
<th>SOF + RBV (16 wk)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 4</td>
<td>97/100</td>
<td>98/95</td>
</tr>
<tr>
<td>End of Tx</td>
<td>100/100</td>
<td>100/95</td>
</tr>
<tr>
<td>SVR12</td>
<td>50/100</td>
<td>69/95</td>
</tr>
</tbody>
</table>

SOF = Sofosbuvir; RBV = Ribavirin

Sofosbuvir + RBV in Treatment-Experienced HCV GT 2 or 3
FUSION Trial: Results

FUSION: SVR12 by Genotype and Treatment Duration

<table>
<thead>
<tr>
<th>Genotype</th>
<th>SOF + RBV (12 wks)</th>
<th>SOF + RBV (16 wks)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GT 2</td>
<td>31/36</td>
<td>30/32</td>
</tr>
<tr>
<td>GT 3</td>
<td>19/64</td>
<td>39/63</td>
</tr>
</tbody>
</table>

SOF = Sofosbuvir; RBV = Ribavirin

Sofosbuvir + RBV in Treatment-Experienced HCV GT 2 or 3 FUSION Trial: Results

FUSION: SVR12 by Liver Disease

<table>
<thead>
<tr>
<th></th>
<th>SOF + RBV (12 wks)</th>
<th>SOF + RBV (16 wks)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Cirrhosis</td>
<td>61/127</td>
<td>48/63</td>
</tr>
<tr>
<td>Cirrhosis</td>
<td>31/36</td>
<td>21/32</td>
</tr>
</tbody>
</table>

SOF = Sofosbuvir; RBV = Ribavirin

Sofosbuvir + RBV in Treatment-Experienced HCV GT 2 or 3
FUSION Trial: Results

FUSION: SVR12 by Genotype, Cirrhosis, and Duration of Therapy

Conclusions: “Our findings suggest that 12 weeks of treatment with sofosbuvir and ribavirin can be an effective option for patients with HCV genotype 2 infection. However, for patients with genotype 3 infection, particularly those who have cirrhosis or who have not had a response to prior treatment with interferon, extending the duration of treatment to 16 weeks may provide an additional benefit.”

*Note: This conclusion pertains to both the FUSION and POSITRON trials, which were published in tandem.
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](http://www.hepatitisc.uw.edu)

**Hepatitis Web Study**


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