Simeprevir + Sofosbuvir in GT1 with Cirrhosis
OPTIMIST-2 Trial

**OPTIMIST 2 Trial: Features**

- **Design**: Randomized, phase 3, open-label, single-arm trial evaluating the safety and efficacy of sofosbuvir plus simeprevir for 12 weeks in treatment-naive or treatment-experienced patients HCV genotype 1 patients with compensated cirrhosis.

- **Setting**: multicenter in United States and Canada.

- **Entry Criteria**
  - Chronic HCV Genotype 1 infection
  - Studies indicating cirrhosis with compensation
  - Age 18-70
  - HCV RNA greater than 10,000 IU/mL
  - Any treatment history allowed

- **Exclusion**
  - Hepatic decompensation, or non-HCV-related liver disease
  - Coinfection with HBV or HIV

- **End-Points**: Primary = SVR12 by intent-to-treat analysis

Simeprevir + Sofosbuvir for HCV GT 1 with Cirrhosis

OPTIMIST-2 Trial: Study Design

GT-1
Naïve/Experienced
Compensated Cirrhosis

n = 103

Simeprevir + Sofosbuvir

SVR12

Drug Dosing
Simeprevir: 150 mg once daily
Sofosbuvir: 400 mg once daily

Simeprevir + Sofosbuvir for HCV GT 1 with Cirrhosis
OPTIMIST-2 Trial: Results

OPTIMIST 2: SVR12, by Treatment Experience

SVR12 = sustained virologic response at 12 weeks

Simeprevir + Sofosbuvir for HCV GT 1 with Cirrhosis

OPTIMIST-2 Trial: Results

OPTIMIST 2: SVR12, by Genotype 1 Subtype

Simeprevir + Sofosbuvir x 12 weeks

Patients (%) with SVR 12

<table>
<thead>
<tr>
<th>Genotype</th>
<th>SVR12</th>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>GT1a</td>
<td>83</td>
<td>60/72</td>
</tr>
<tr>
<td>GT1a</td>
<td>74</td>
<td>25/34</td>
</tr>
<tr>
<td>GT1a</td>
<td>92</td>
<td>35/38</td>
</tr>
<tr>
<td>GT1b</td>
<td>84</td>
<td>26/31</td>
</tr>
</tbody>
</table>

SVR12 = sustained virologic response at 12 weeks

Conclusions: “Simeprevir + sofosbuvir for 12 weeks achieved superiority in SVR12 rates versus the historical control in treatment-naive and treatment-experienced HCV GT1-infected patients with cirrhosis and was generally safe and well tolerated.”
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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