Simeprevir + Sofosbuvir in GT1 without Cirrhosis
OPTIMIST-1 Trial

Simeprevir + Sofosbuvir for HCV GT 1 without Cirrhosis

OPTIMIST-1 Trial: Study Features

<table>
<thead>
<tr>
<th>OPTIMIST 1 Trial: Features</th>
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<tbody>
<tr>
<td><strong>Design</strong>: Randomized, phase 3, open-label, trial evaluating the safety and efficacy of sofosbuvir plus simeprevir for 8 or 12 weeks in treatment-naive or treatment-experienced HCV genotype 1 patients without cirrhosis.</td>
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<td><strong>Setting</strong>: Multicenter in United States and Canada</td>
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<td><strong>Entry Criteria</strong></td>
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<tr>
<td>- Chronic HCV Genotype 1a or 1b</td>
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<td>- Documented lack of cirrhosis</td>
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<td>- Age 18-70</td>
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<td>- HCV RNA greater than 10,000 IU/mL</td>
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<td>- Treatment experienced required to have ≥1 INF-based regimen +/- RBV</td>
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<td><strong>Exclusion</strong></td>
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<td>- Cirrhosis, hepatic decompensation, or non-HCV-related liver disease</td>
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<td>- Coinfection with HBV or HIV</td>
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<td><strong>End-Points</strong>: Primary = SVR12 by intent-to-treat analysis</td>
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Simeprevir + Sofosbuvir for HCV GT 1 without Cirrhosis

OPTIMIST-1 Trial: Study Design

- **GT-1 Naïve/Experienced Noncirrhotic**
  - n = 155
  - Simeprevir + Sofosbuvir
  - SVR12

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

Simeprevir + Sofosbuvir for HCV GT 1 without Cirrhosis
OPTIMIST-1 Trial: Results

OPTIMIST 1: SVR12, by Treatment Experience

SVR12 = sustained virologic response at 12 weeks

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OPTIMIST-1 Trial: Results

OPTIMIST 1: SVR12, by Genotype 1 Subtype

OPTIMIST-1 Trial: Results
Simeprevir + Sofosbuvir for HCV GT 1 without Cirrhosis

SVR12 = sustained virologic response at 12 weeks

Conclusions: “Simeprevir plus sofosbuvir for 12 weeks is highly effective in the treatment of HCV GT1-infected patients without cirrhosis, including those with Q80K.”

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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