Simeprevir in HIV Coinfection, GT-1 C212 Trial

# Simeprevir + PEG + Ribavirin for HCV-HIV Coinfection Study C212: Study Features

## C212 Trial: Features

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td><strong>Design</strong></td>
<td>Open-label, phase 3, trial evaluating simeprevir + PEG + RBV in HCV-HIV and GT 1 (treatment naïve and experienced)</td>
</tr>
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<td><strong>Setting</strong></td>
<td>39 sites in 7 countries</td>
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<tr>
<td><strong>Entry Criteria</strong></td>
<td>- HIV coinfection; HCV genotype 1 - Treatment naïve or treatment experienced - Group 1: HCV treatment-naïve or prior relapse - Group 2: Prior partial or null response or cirrhosis - CD4 ≥ 200 if on stable ARV therapy; CD4 ≥ 500 if no ARV therapy - Stable antiretroviral therapy = HIV RNA &lt; 50 copies/ml &gt; 8 weeks</td>
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<tr>
<td><strong>Patient Characteristics</strong></td>
<td>- N = 106 HCV-HIV coinfected patients - Race: white (82%); black (14%) - Baseline Median CD4 (cells/mm$^3$): 629 cells/mm$^3$</td>
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<tr>
<td><strong>Primary End-Points</strong></td>
<td>Efficacy (SVR12), safety, and impact on HIV</td>
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Simeprevir + PEG + Ribavirin for HCV-HIV Coinfection
Study C212: Design

**Drug Dosing**
- Simeprevir: 150 mg once daily
- Peginterferon alfa-2a (PEG): 180 mcg/week
- Ribavirin (RBV) weight-based (in 2 divided doses): 1000 mg if < 75kg or 1200 mg/day if ≥ 75kg

Simeprevir + PEG + Ribavirin for HCV-HIV Coinfection
Study C212: Results

C212: SVR12 by Prior Treatment Status

<table>
<thead>
<tr>
<th>Treatment Status</th>
<th>Patients (%) with SVR12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>74/106</td>
</tr>
<tr>
<td>Treatment-Naïve</td>
<td>79/53</td>
</tr>
<tr>
<td>Relapsers</td>
<td>87/15</td>
</tr>
<tr>
<td>Partial</td>
<td>70/10</td>
</tr>
<tr>
<td>Null</td>
<td>57/28</td>
</tr>
</tbody>
</table>

Simeprevir + PEG + Ribavirin for HCV-HIV Coinfection Study C212: Results

C212: SVR12 by GT1 Subtype and Baseline NS3 Q80K Polymorphism

Simeprevir + PEG + Ribavirin for HCV-HIV Coinfection
Study C212: Results

C212: SVR12 by Fibrosis Stage and Prior History

[Bar chart showing SVR12 by fibrosis stage and prior history for treatment-naïve and treatment-experienced groups]

Overall: 80/45, Treatment-Naïve: 89/27, Relapsers: 78/9, Treatment-Experienced: METAVIR F0-F2 64/14, METAVIR F3-F4 57/4, Partial: METAVIR F0-F2 50/1, METAVIR F3-F4 67/2, Null: METAVIR F0-F2 57/4, METAVIR F3-F4 60/6

Simeprevir + PEG + Ribavirin for HCV-HIV Coinfection Study C212: Results

C212: SVR12 by IL28B Genotype

**Conclusions:** “Simeprevir was generally well tolerated with safety similar to that observed in HCV-monoinfected patients and high SVR12 rates in HCV treatment-naive patients, prior relapsers, prior partial responders, and prior null responders with HIV-1 coinfection.”
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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