

Treatment Naïve and Treatment Experienced

Simeprevir in HIV Coinfection, GT-1 C212 Trial

Dieterich D, et al. 14th European AIDS Conference. Abstract PS9/6.

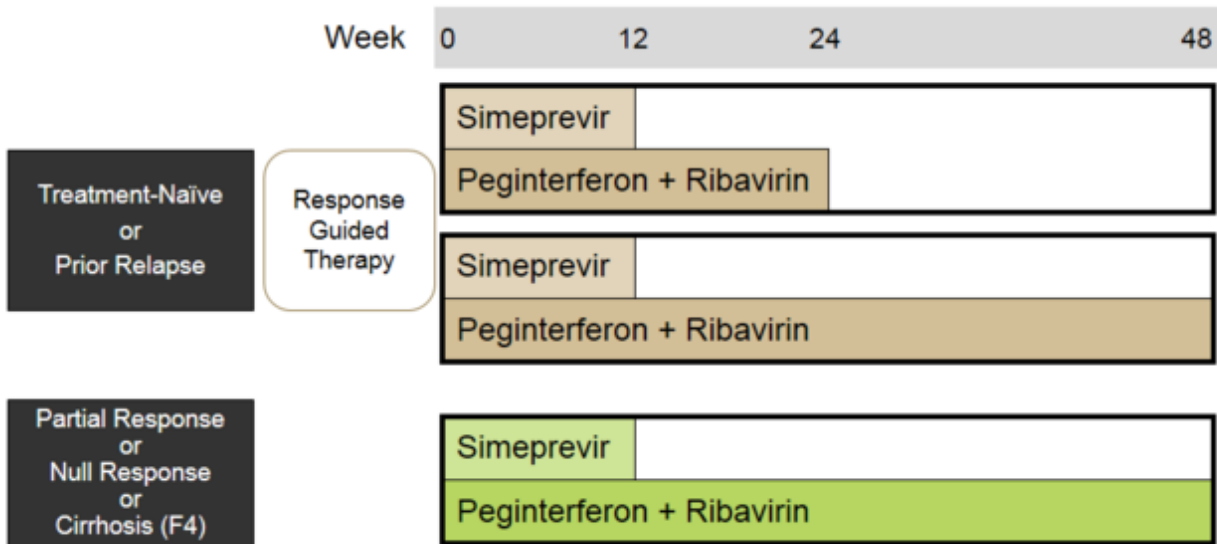
Simeprevir + PEG + Ribavirin for HCV-HIV Coinfection

C212 Trial: Study Features

C212 Trial: Features

- **Design:** Open-label, phase 3, trial in HCV-HIV and GT 1 (treatment naïve and experienced)
- **Setting:** International
- **Entry Criteria**
 - 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 \geq 200 if on stable ARV therapy; CD4 \geq 500 if no ARV therapy
 - Stable antiretroviral therapy = HIV RNA < 50 copies/ml > 8 weeks
- **Patient Characteristics**
 - N = 106 HCV-HIV coinfecting patients
 - Race: white (82%); black (14%)
 - Baseline Median CD4 (cells/mm³): 629 cells/mm³
- **Primary End-Points:** Efficacy (SVR12), safety, and impact on HIV

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



Drug Dosing

Simeprevir: 150 mg once daily

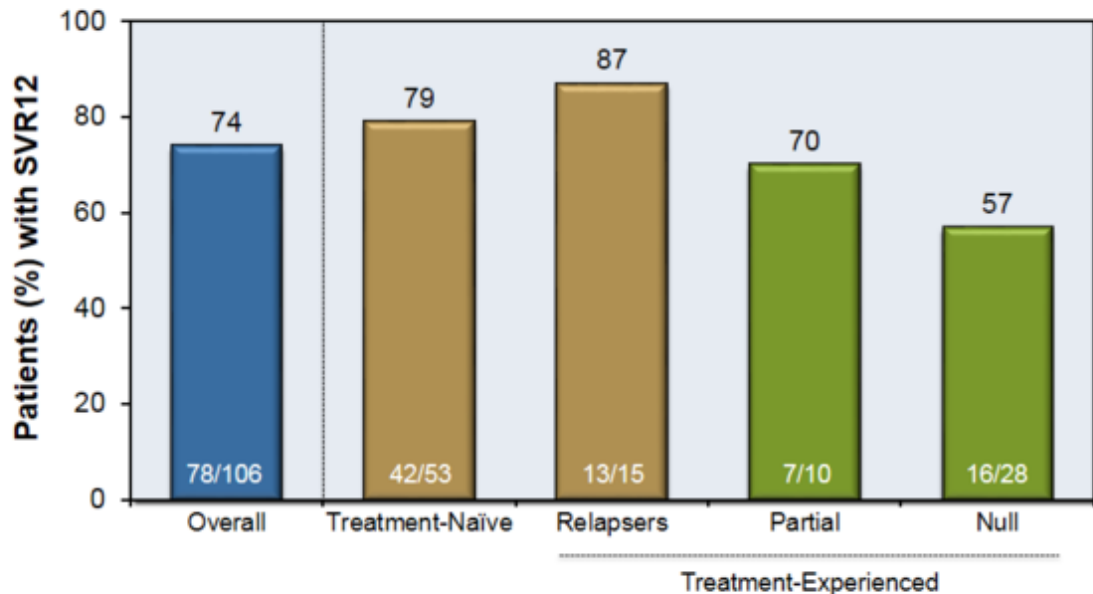
Peginterferon alfa-2a (PEG): 180 mcg/week

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

C212 Trial: Results

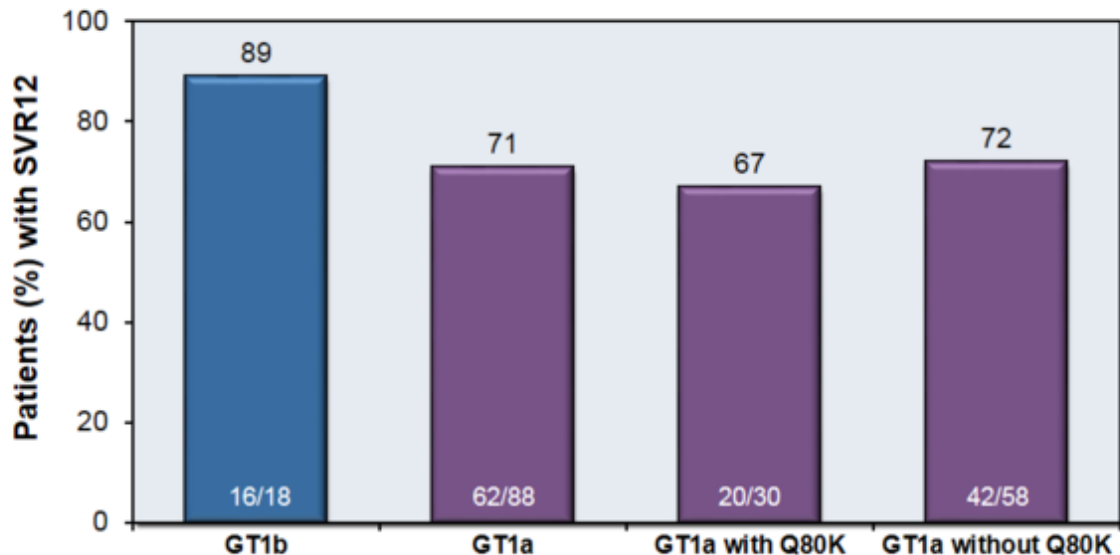
C212: SVR12 by Prior Treatment Status



Simeprevir + PEG + Ribavirin for HCV-HIV Coinfection

C212 Trial: Results

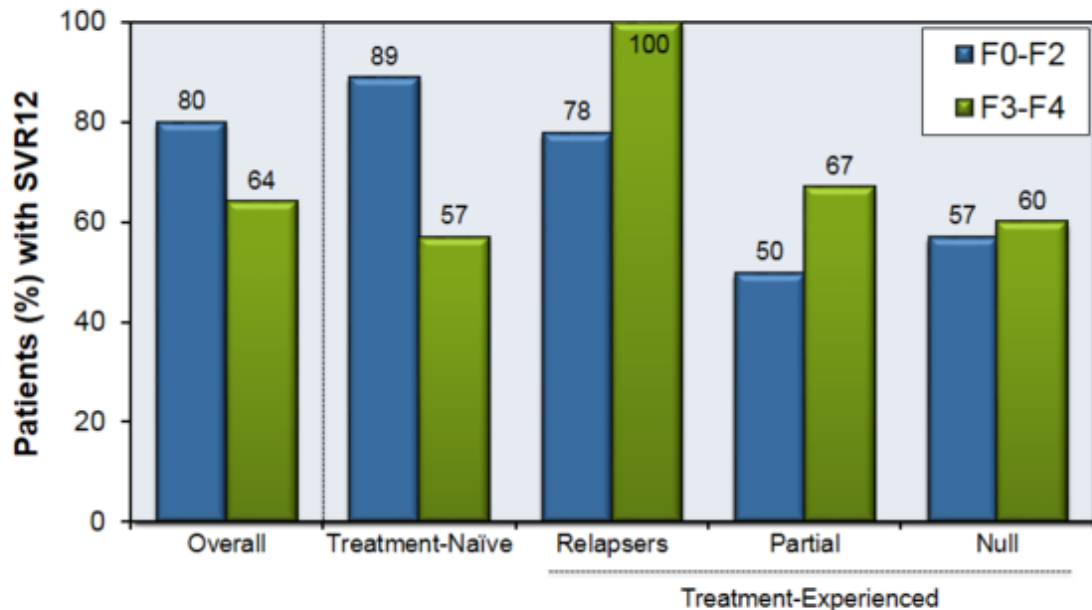
C212: SVR12 by GT1 Subtype and Baseline NS3 Q80K Polymorphism



Simeprevir + PEG + Ribavirin for HCV-HIV Coinfection

C212 Trial: Results

C212: SVR12 by Fibrosis Stage and Prior History



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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