Treatment Naïve and Treatment Experienced

Simeprevir with Peginterferon and Ribavirin in GT-4 RESTORE

Moreno C, et al. 49th EASL. April 2014: Abstract P1319.

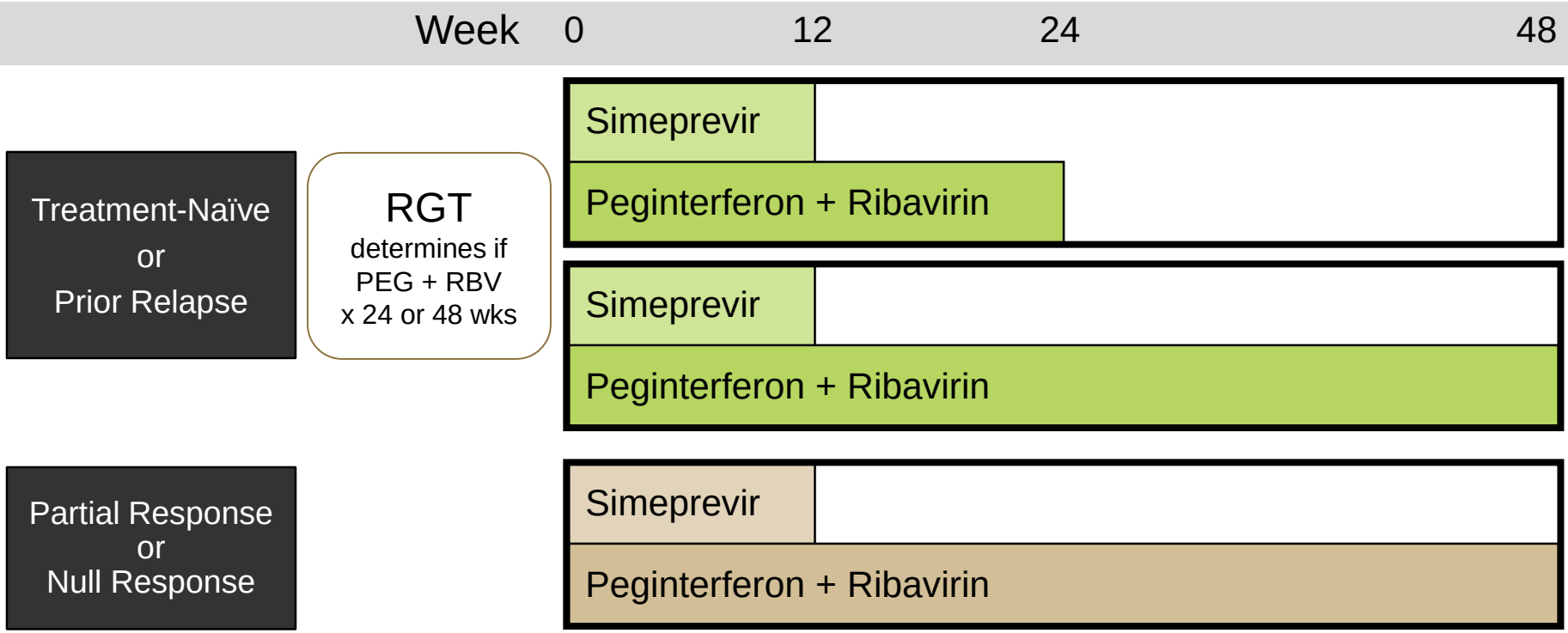
Simeprevir + Peginterferon + Ribavirin in Genotype 4
RESTORE: Study Features

RESTORE Trial: Features

- **Design**: Open-label, phase 3, study evaluating simeprevir + PEG + RBV for treatment naïve and experienced patients with genotype 4 chronic HCV
- **Setting**: Multicenter and International
- **Entry Criteria**
  - Chronic HCV genotype 4 (n = 107)
  - Treatment naïve (n = 35) or treatment experienced relapsers (n = 22)
  - Experienced (Nonresponder): partial (n = 10), null (n = 40)
- **Patient Characteristics**
  - Sex: male 79%
  - Race: white (72%); black (28%)
  - Median age: 49
  - IL genotype: 7.5% CC
  - METAVIR Fibrosis Stage: F4 = 29%; F3 = 14%
- **Primary End-Points**: Efficacy (SVR12)

Source: Moreno C, et al. 49th EASL. April 2014: Abstract P1319.

Simeprevir + Peginterferon + Ribavirin in Genotype 4 RESTORE: Study Design



Response Guided Therapy (RGT) Criteria: Week 4 HCV RNA < 25 IU/mL (detectable or undetectable) and Week 12 HCV RNA < 25 IU/mL (undetectable)

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

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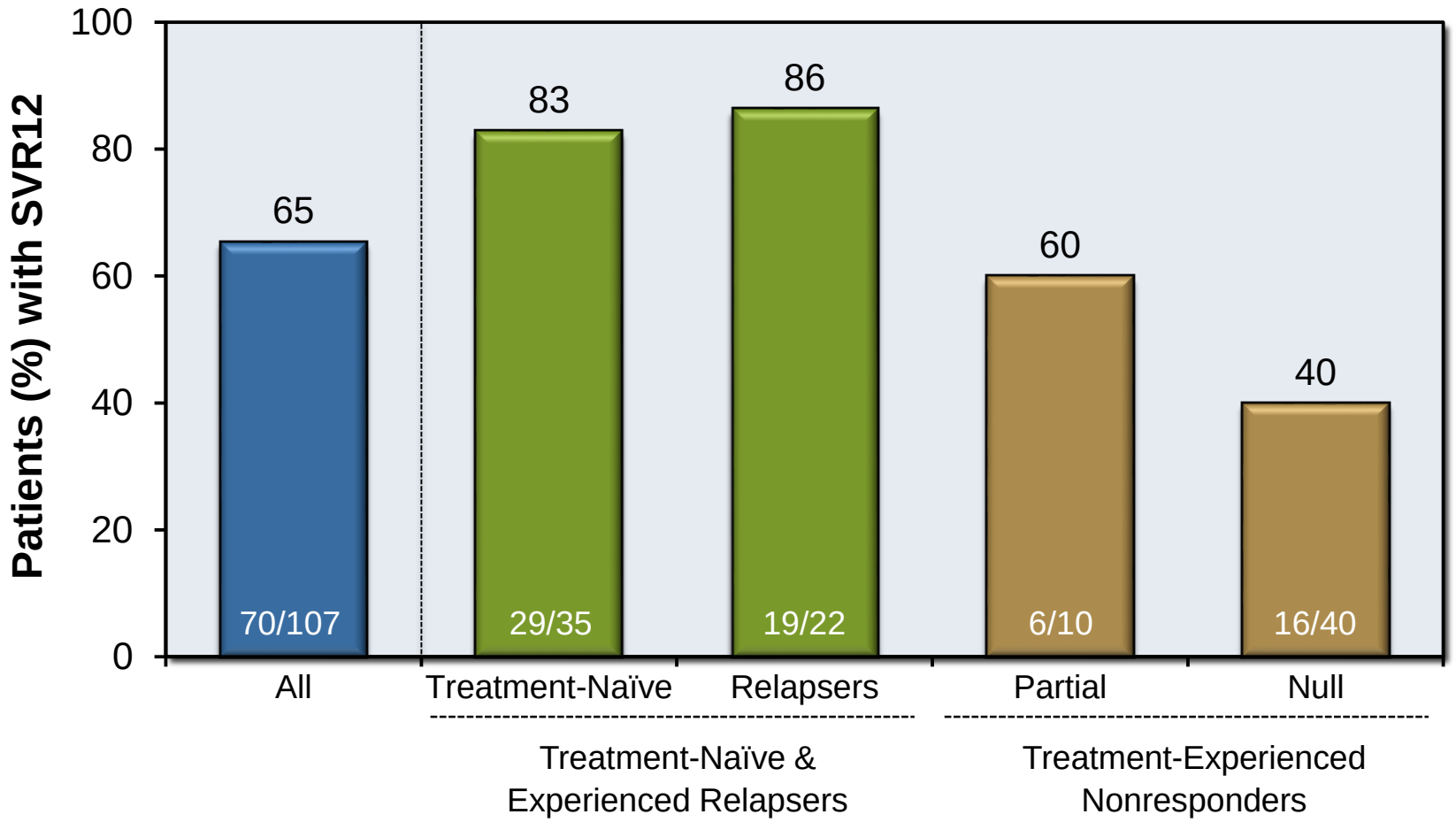
Simeprevir + Peginterferon + Ribavirin in Genotype 4
RESTORE: Results

RESTORE: SVR12 by Prior Treatment Status



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Hepatitis web study

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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Hepatitis web study