

Treatment Naïve and Treatment Experienced

# Simeprevir + Sofosbuvir in GT1 with Cirrhosis OPTIMIST-2 Trial

Lawitz E, et al. Hepatology. 2016;64:360-9.

# Simeprevir + Sofosbuvir for HCV GT 1 with Cirrhosis

## OPTIMIST-2 Trial: Study Features

### 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

Week

0

12

24

**GT-1**

Naïve/Experienced

Compensated Cirrhosis

n = 103

**Simeprevir + Sofosbuvir**

SVR12

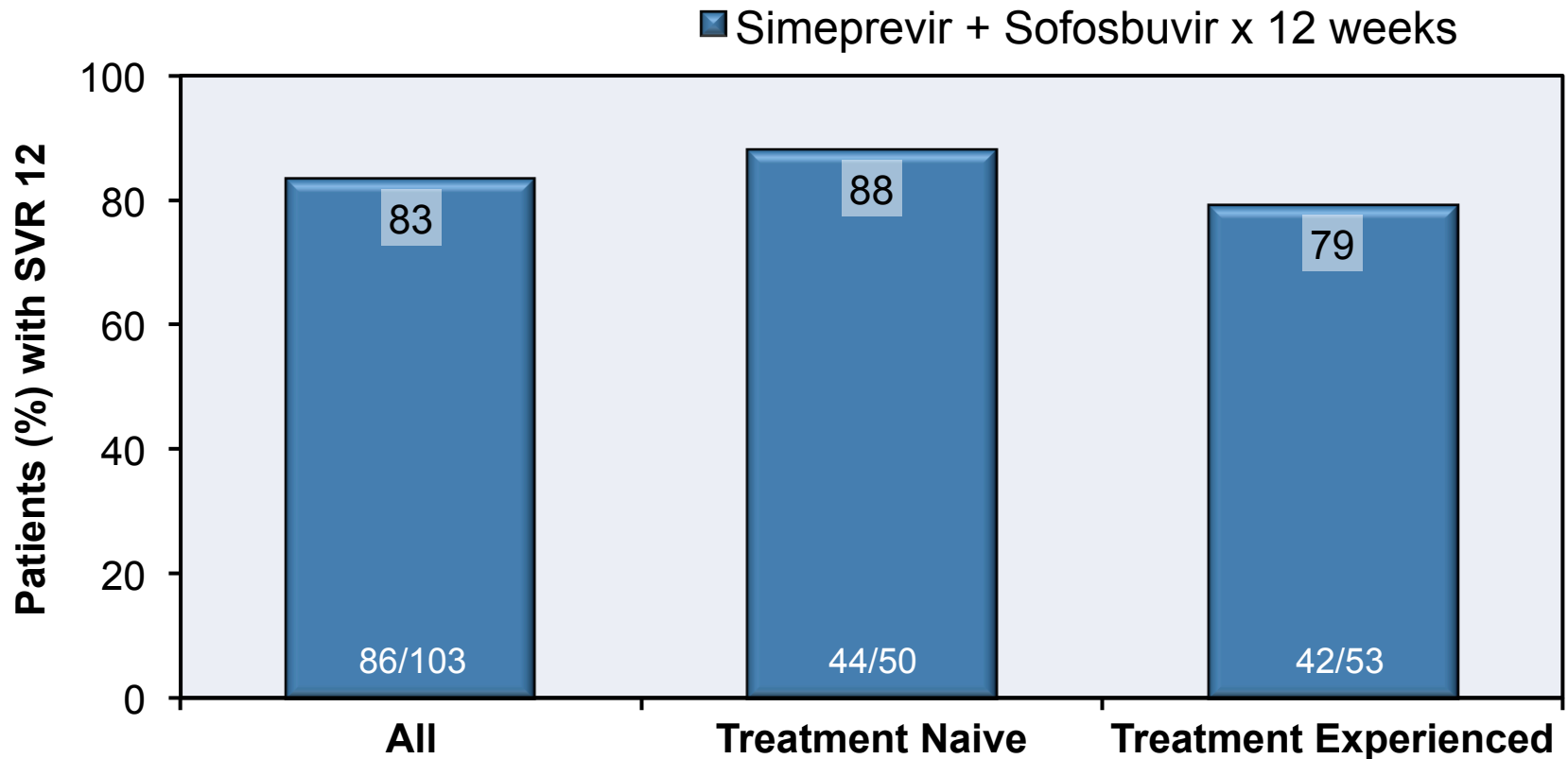
## Drug Dosing

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

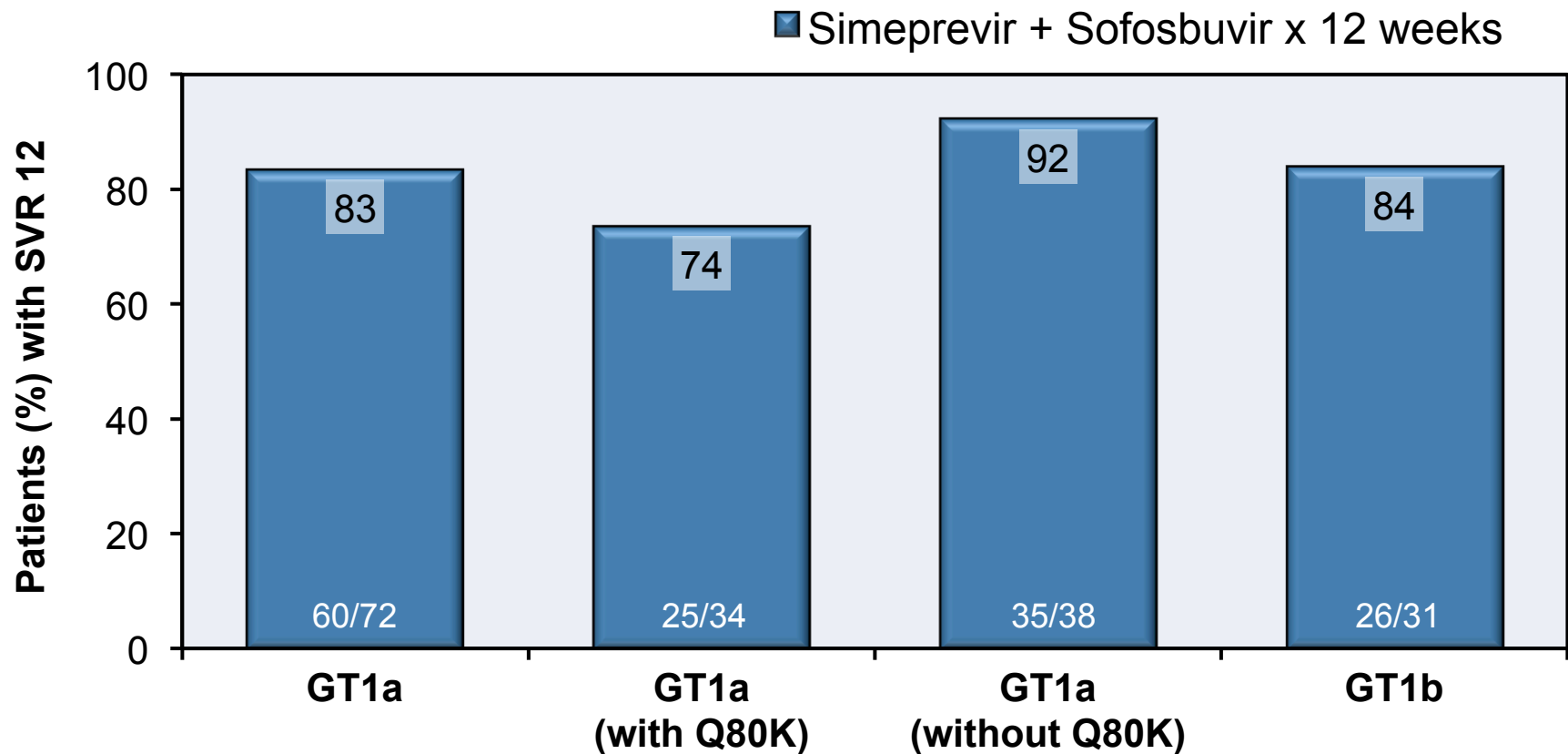


SVR12 = sustained virologic response at 12 weeks

Source: Lawitz E, et al. *Hepatology*. 2016;64:360-9.

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

## OPTIMIST 2: SVR12, by Genotype 1 Subtype



SVR12 = sustained virologic response at 12 weeks

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

**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](http://www.hepatitisc.uw.edu)

Hepatitis Web Study  
<http://depts.washington.edu/hepstudy/>

Funded by a grant from the Centers for Disease Control and Prevention.