

Treatment Naïve and Treatment Experienced

Simeprevir + Sofosbuvir in GT1 without Cirrhosis OPTIMIST-1 Trial

Kwo P, et al. Hepatology. 2016;64:370-80.

Simeprevir + Sofosbuvir for HCV GT 1 without Cirrhosis

OPTIMIST-1 Trial: Study Features

OPTIMIST 1 Trial: Features

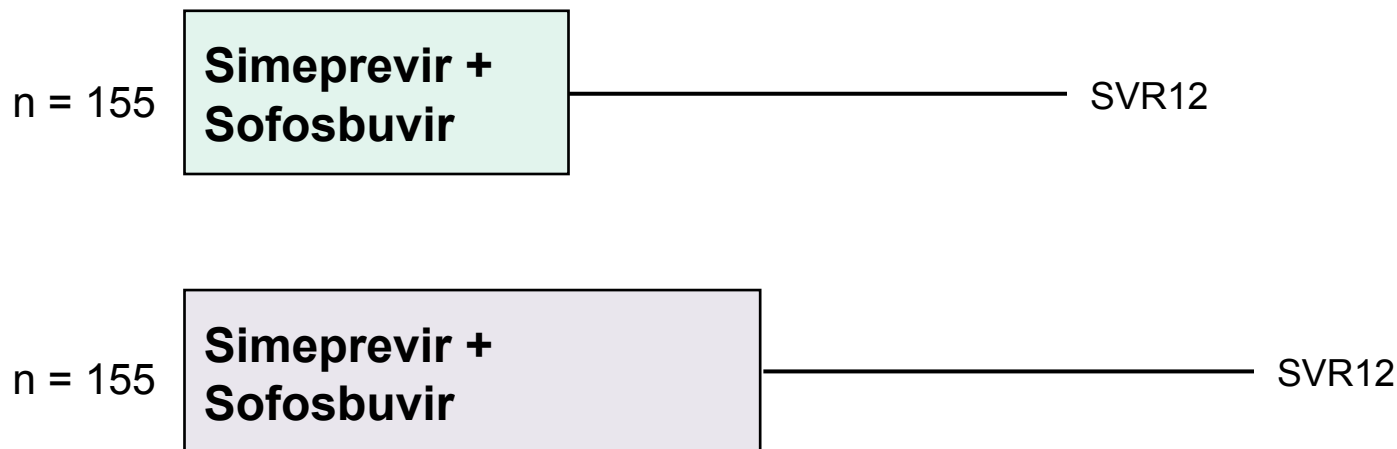
- **Design:** Randomized, phase 3, open-label, trial evaluating the safety and efficacy of sofosbuvir plus simeprevir for 8 or 12 weeks in treatment-naive or treatment-experienced HCV genotype 1 patients without cirrhosis
- **Setting:** Multicenter in United States and Canada
- **Entry Criteria**
 - Chronic HCV Genotype 1a or 1b
 - Documented lack of cirrhosis
 - Age 18-70
 - HCV RNA greater than 10,000 IU/mL
 - Treatment experienced required to have ≥ 1 INF-based regimen +/- RBV
- **Exclusion**
 - Cirrhosis, 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 without Cirrhosis

OPTIMIST-1 Trial: Study Design

Week 0 8 12 20 24

GT-1
Naïve/Experienced
Noncirrhotic



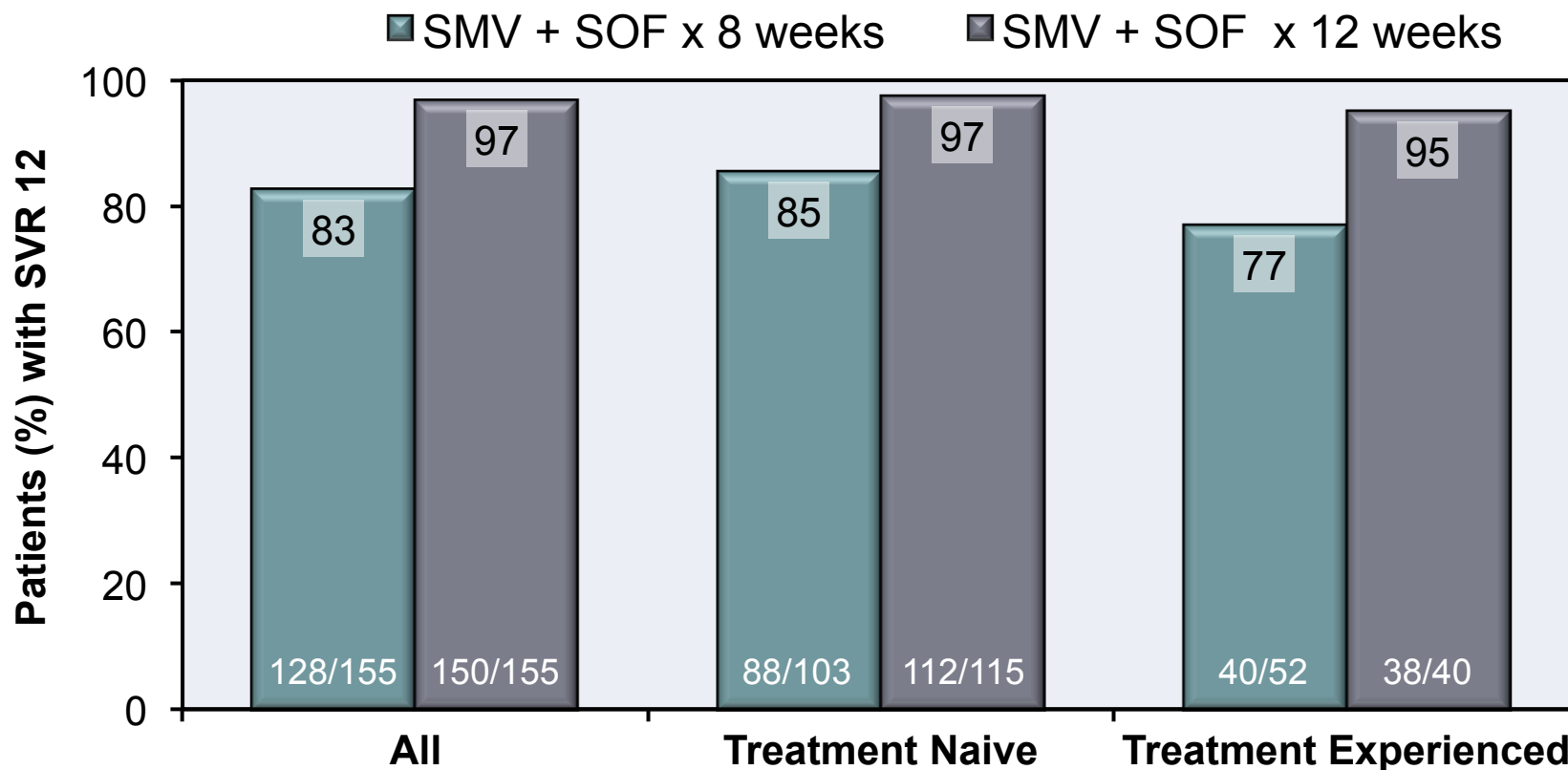
Drug Dosing

Simeprevir: 150 mg once daily

Sofosbuvir: 400 mg once daily

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

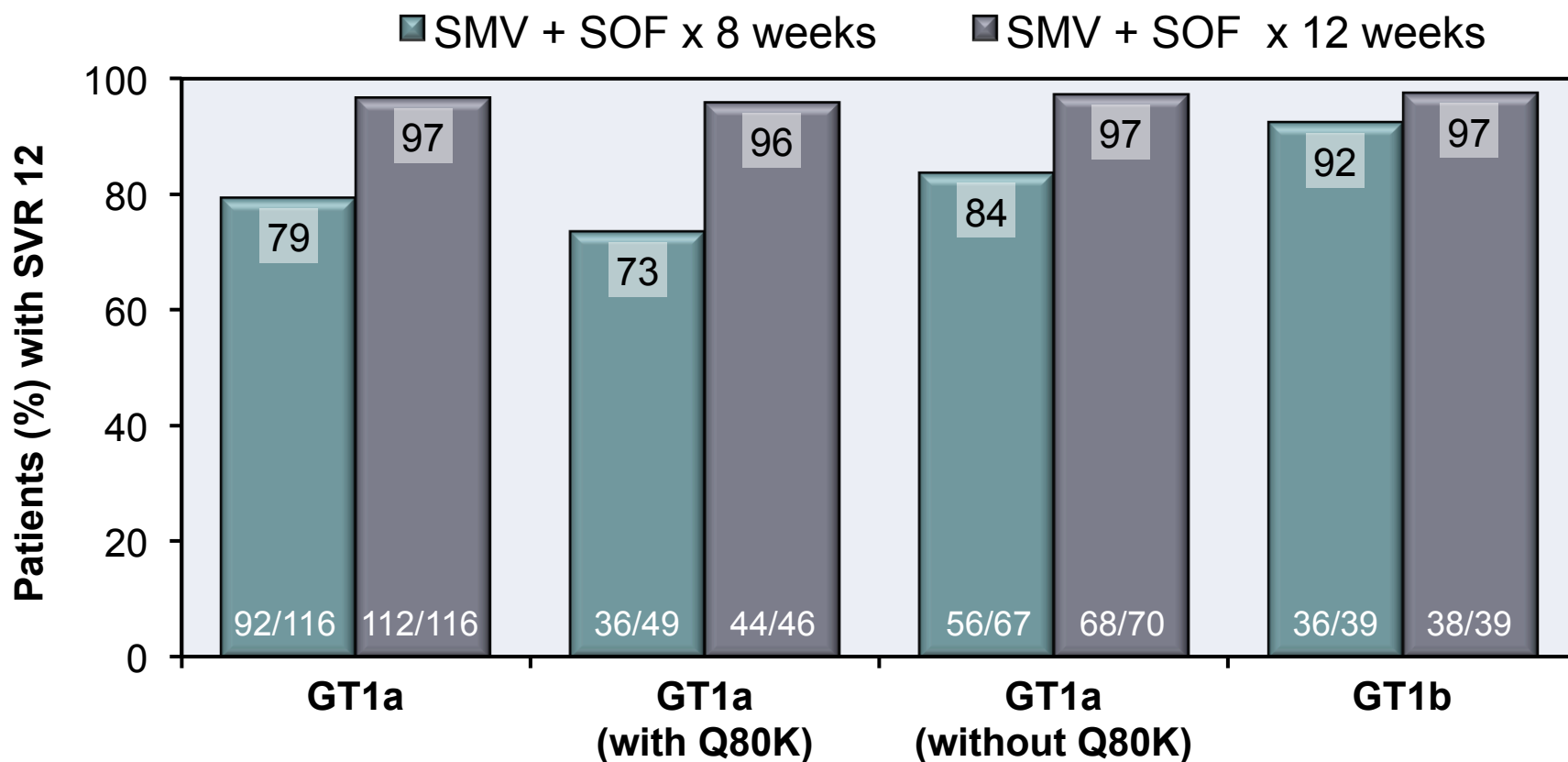
OPTIMIST 1: SVR12, by Treatment Experience



SVR12 = sustained virologic response at 12 weeks

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

OPTIMIST 1: SVR12, by Genotype 1 Subtype



SVR12 = sustained virologic response at 12 weeks

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

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

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

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