

Treatment Experienced

Sofosbuvir + Peginterferon + Ribavirin in Genotype 2 or 3
LONESTAR-2

Lawitz E, et al. 64th AASLD; Washington, DC. 2013. Abstract LB-4.

Sofosbuvir + PEG + RBV in Treatment-Experienced HCV GT 2 or 3

LONESTAR-2 Trial: Features

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- **Design:** Open-label, single-arm, phase 2 trial of 12-week course of sofosbuvir + ribavirin in treatment-experienced patients with HCV GT 2 or 3
- **Setting:** Texas Liver Institute
- **Entry Criteria**
 - N = 47 patients with chronic hepatitis C
 - Previously failed treatment with peginterferon plus ribavirin
 - Excluded if coinfecting with HIV or HBV
 - HCV genotype 2 (49%) or 3 (51%)
 - Compensated cirrhosis allowed
- **Regimen (All x 12 weeks)**
 - Sofosbuvir: 400 mg once daily
 - Peginterferon alfa-2a: 180 µg once weekly
 - Ribavirin (weight based): 1000-1200 mg/day in 2 divided doses
- **Primary End-Point:** SVR12

Sofosbuvir + PEG + RBV in Treatment-Experienced HCV GT 2 or 3 LONESTAR-2 Trial: Patient Demographics

Baseline Characteristic	SOF + PEG + RBV x 12 weeks (n = 47)
Age, mean (range)	56 (39-72)
Male, n (%)	32 (68)
White, n (%)	45 (96)
Hispanic, n (%)	21 (45)
Mean Body Mass Index (BMI) kg/m ² (range)	31 (21-53)
IL28B CC, n (%)	17 (36)
HCV GT3	24 (51)
Mean baseline HCV RNA, log ₁₀ IU/ml (range)	6.2 (4.0-7.2)
Cirrhosis, %	26 (55)
Prior Relapse / virologic breakthrough	40 (85)

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Sofosbuvir + PEG + RBV in Treatment-Experienced HCV GT 2 or 3 LONESTAR-2 Trial: Design

Week

0

12

24

GT 2 or 3

N = 47

**Sofosbuvir +
Peginterferon + Ribavirin**

SVR12

Drug Dosing

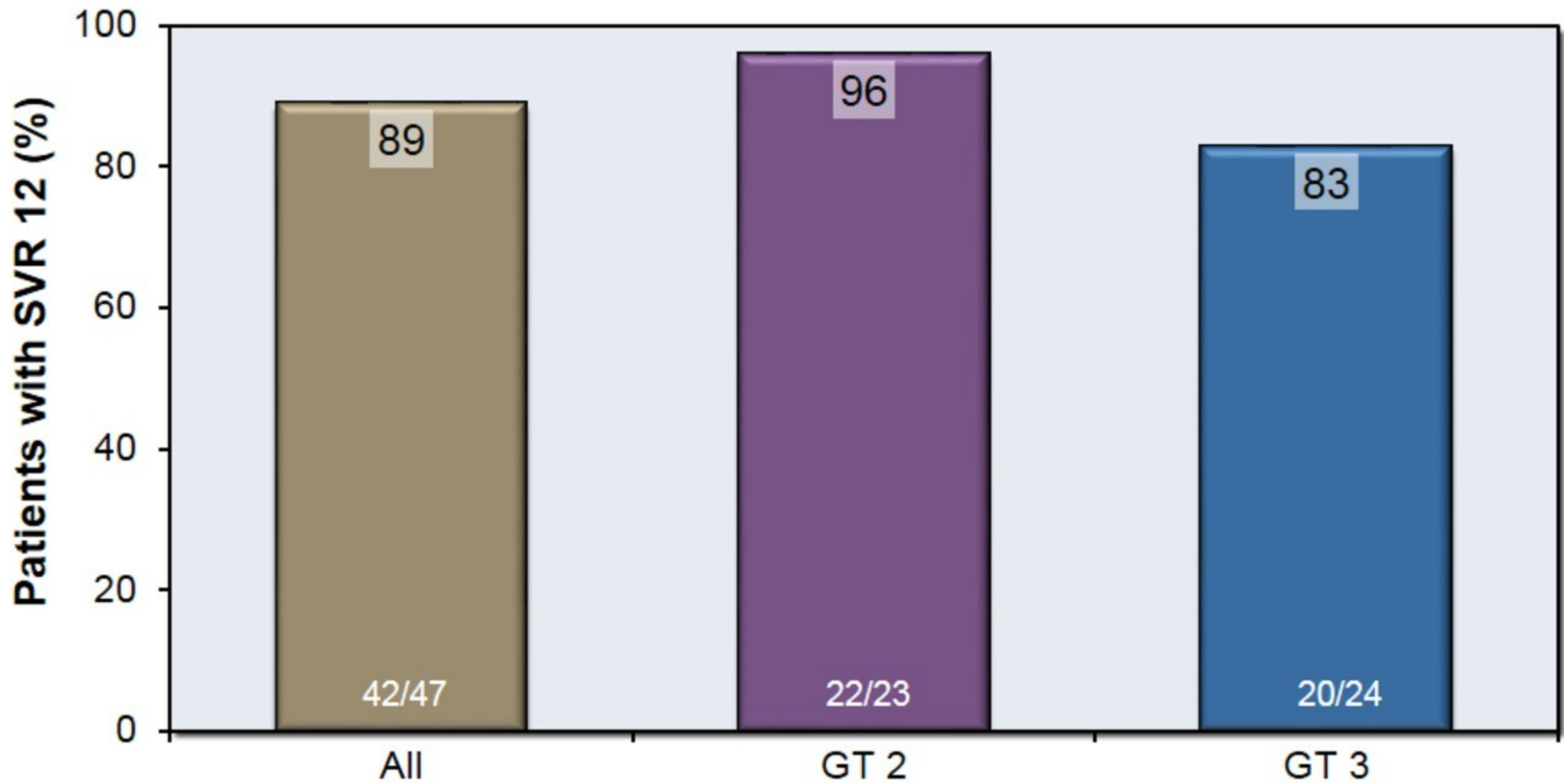
Sofosbuvir: 400 mg once daily

Peginterferon alfa-2a: 180 µg once weekly

Ribavirin (weight-based and in 2 divided doses): 1000 mg/day if < 75 kg or 1200 mg/day if ≥ 75 kg

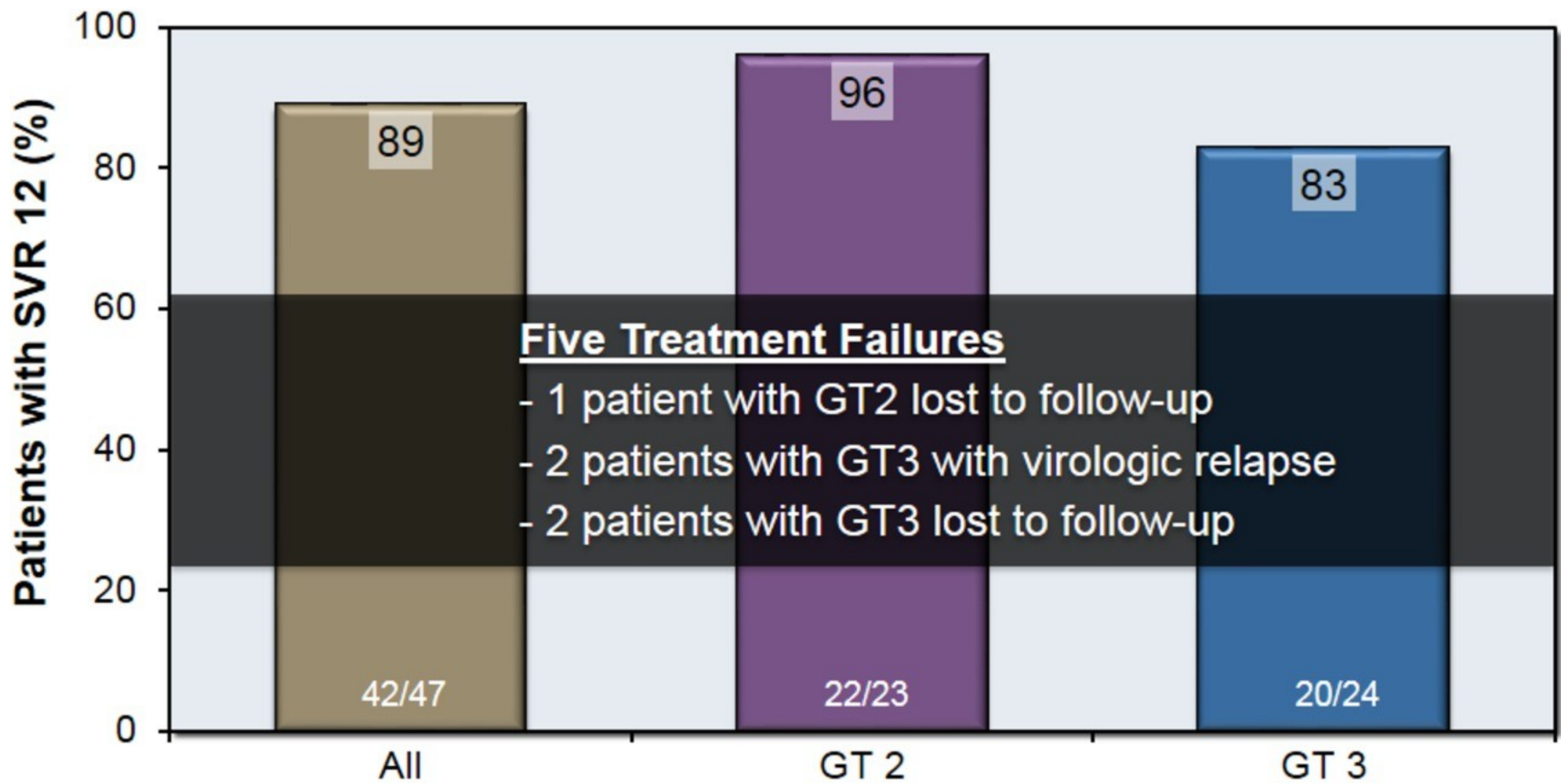
Sofosbuvir + PEG + RBV in Treatment-Experienced HCV GT 2 or 3 LONESTAR-2 Trial: Results

SVR12 in Treatment-Experienced by HCV Genotype



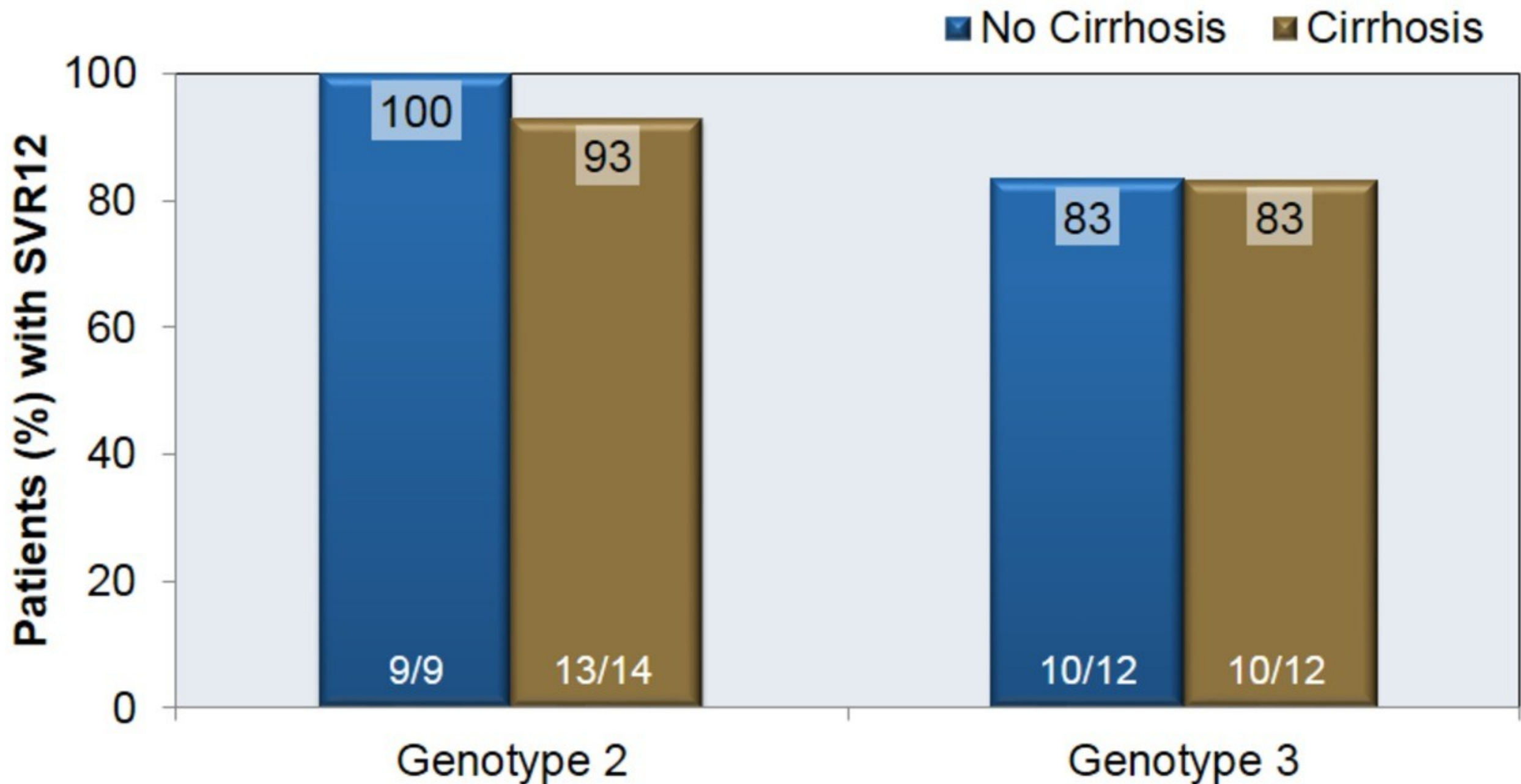
Sofosbuvir + PEG + RBV in Treatment-Experienced HCV GT 2 or 3 LONESTAR-2 Trial: Results

SVR12 in Treatment-Experienced by HCV Genotype



Sofosbuvir + PEG + RBV in Treatment-Experienced HCV GT 2 or 3 LONESTAR-2 Trial: Results

LONESTAR-2 Trial: SVR12 by Cirrhosis Status



Sofosbuvir + PEG + RBV in Treatment-Experienced HCV GT 2 or 3 LONESTAR-2 Trial: Adverse Events

LONESTAR-2: Adverse Events in $\geq 15\%$ of Patients	
Preferred Term, n (%)	SOF + PEG + RBV x 12 weeks (n = 47)
Any Adverse Event	45 (96)
Flu-like Symptoms	26 (55)
Fatigue	15 (32)
Anemia	14 (30)
Neutropenia	11 (23)
Nausea	8 (17)
Headache	7 (15)
Rash	7 (15)
Thrombocytopenia	7 (15)

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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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