

Treatment Experienced

Ledipasvir-Sofosbuvir Retreatment with HCV Genotype 1 NIAID Retreatment

Osinusi A, et al. Ann Intern Med. 2014;161:634-8.

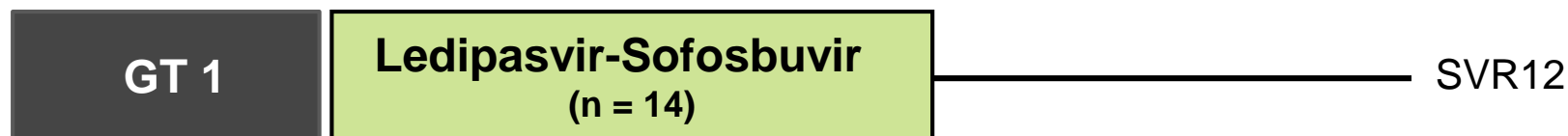
Ledipasvir-Sofosbuvir Retreatment of SOF + RBV Failure in HCV GT 1 NIAID Retreatment Study: Features

NIAID Retreatment Trial

- **Design:** Open-label, phase 2a, using fixed-dose combination of ledipasvir-sofosbuvir for 12 weeks in patients with GT1 HCV who previously had failed a 24-week treatment course of sofosbuvir plus ribavirin
- **Setting:** single site in United States (NIH and community clinics in DC)
- **Entry Criteria**
 - Chronic HCV Genotype 1 (n=14)
 - 18 years or older
 - Prior relapse after a 24-week treatment course of sofosbuvir plus ribavirin
- **Primary End-Point:** SVR12

Ledipasvir-Sofosbuvir Retreatment of SOF + RBV Failure in HCV GT 1 NIAID Retreatment Study: Design

Week 0 12 24



Drug Dosing

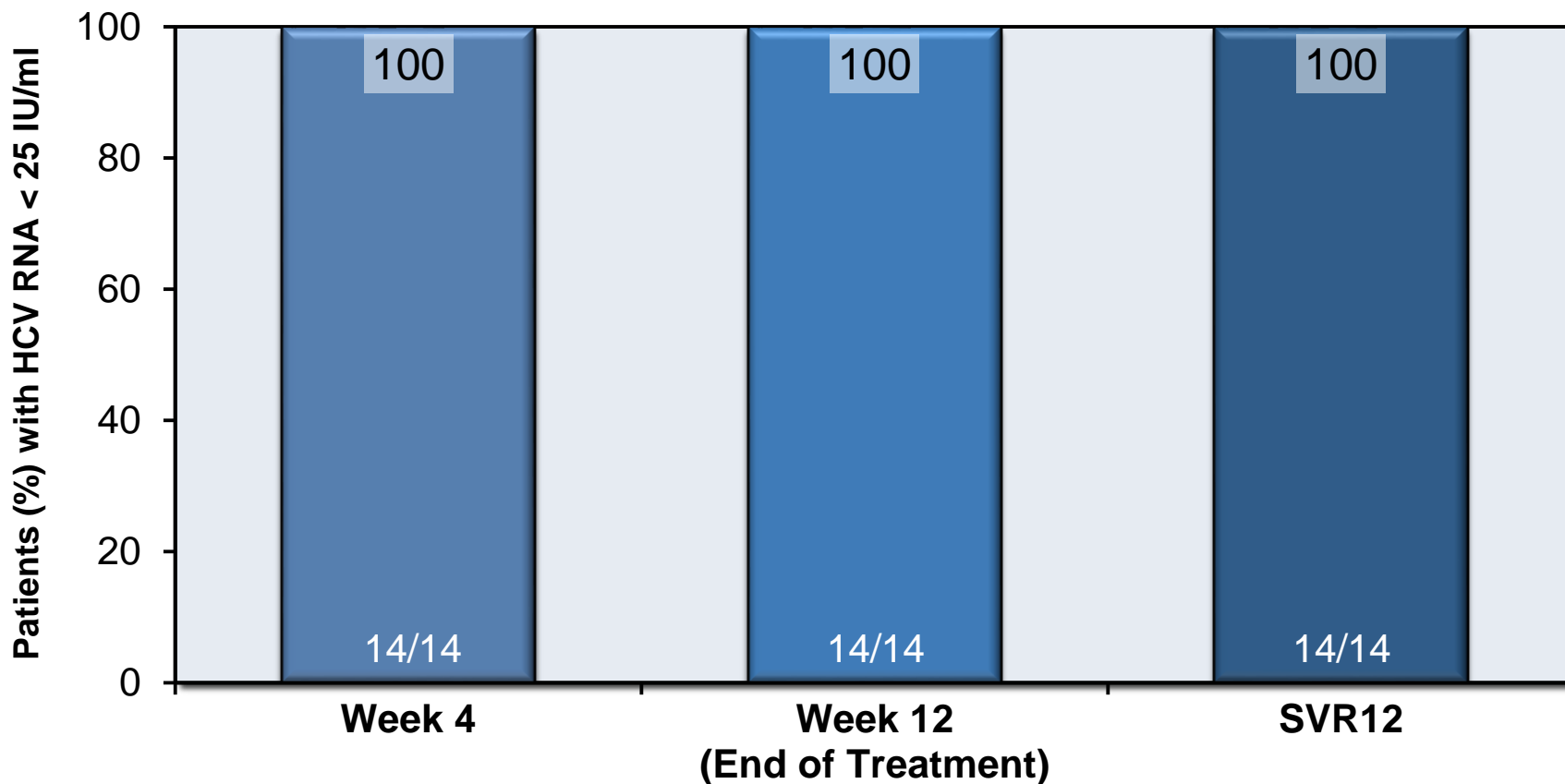
Ledipasvir-sofosbuvir (90/400 mg): fixed dose combination; one pill once daily

Ledipasvir-Sofosbuvir +/- Ribavirin in Treatment-Experienced HCV GT 1 NIAID Retreatment Study: Baseline Characteristics

Baseline Characteristic	Ledipasvir-Sofosbuvir (n=14)
Age, median (range)	59 (48-72)
Male, n (%)	13 (93)
Black race, n (%)	13 (93)
Body Mass Index (BMI) ≥ 30 kg/m ² , n (%)	5 (36)
IL28B genotype CC, n (%)	2 (14)
Knodell Histology Activity Index score, n (%)	
0-1	7 (50)
3-4	7 (50)
HCV GT-1 Subtype	
1a	8 (57)
1b	6 (43)
NS5B S282T Mutation	1 (7)
Median baseline HCV RNA, log ₁₀ IU/ml (range)	6.31 (5.50-6.76)

Ledipasvir-Sofosbuvir +/- Ribavirin in Treatment-experienced HCV GT 1 NIAID Retreatment Study: Results

NIAID Retreatment: Virologic Response



Ledipasvir-Sofosbuvir +/- Ribavirin in Treatment-experienced HCV GT 1 NIAID Retreatment Study: Conclusions

Conclusions: “The fixed-dose combination of sofosbuvir plus ledipasvir was efficacious in a small cohort of patients with HCV GT-1 that relapsed after sofosbuvir plus ribavirin therapy, even in the setting of advanced liver disease. Larger studies are needed to confirm these preliminary efficacy results.”

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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