

Treatment Experienced

# Ledipasvir-Sofosbuvir Retreatment with HCV Genotype 1 NIAID Retreatment

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

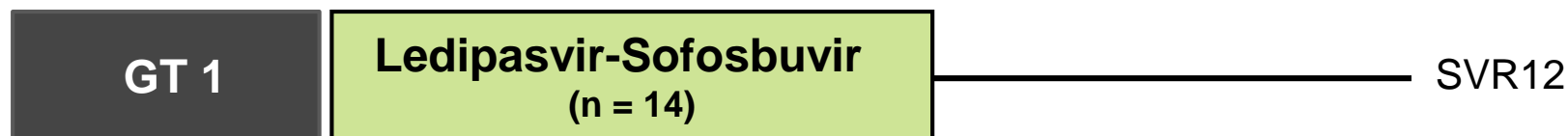
# Ledipasvir-Sofosbuvir Retreatment of SOF + RBV Failure in HCV GT 1 NIAID Retreatment Study: Features

## 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

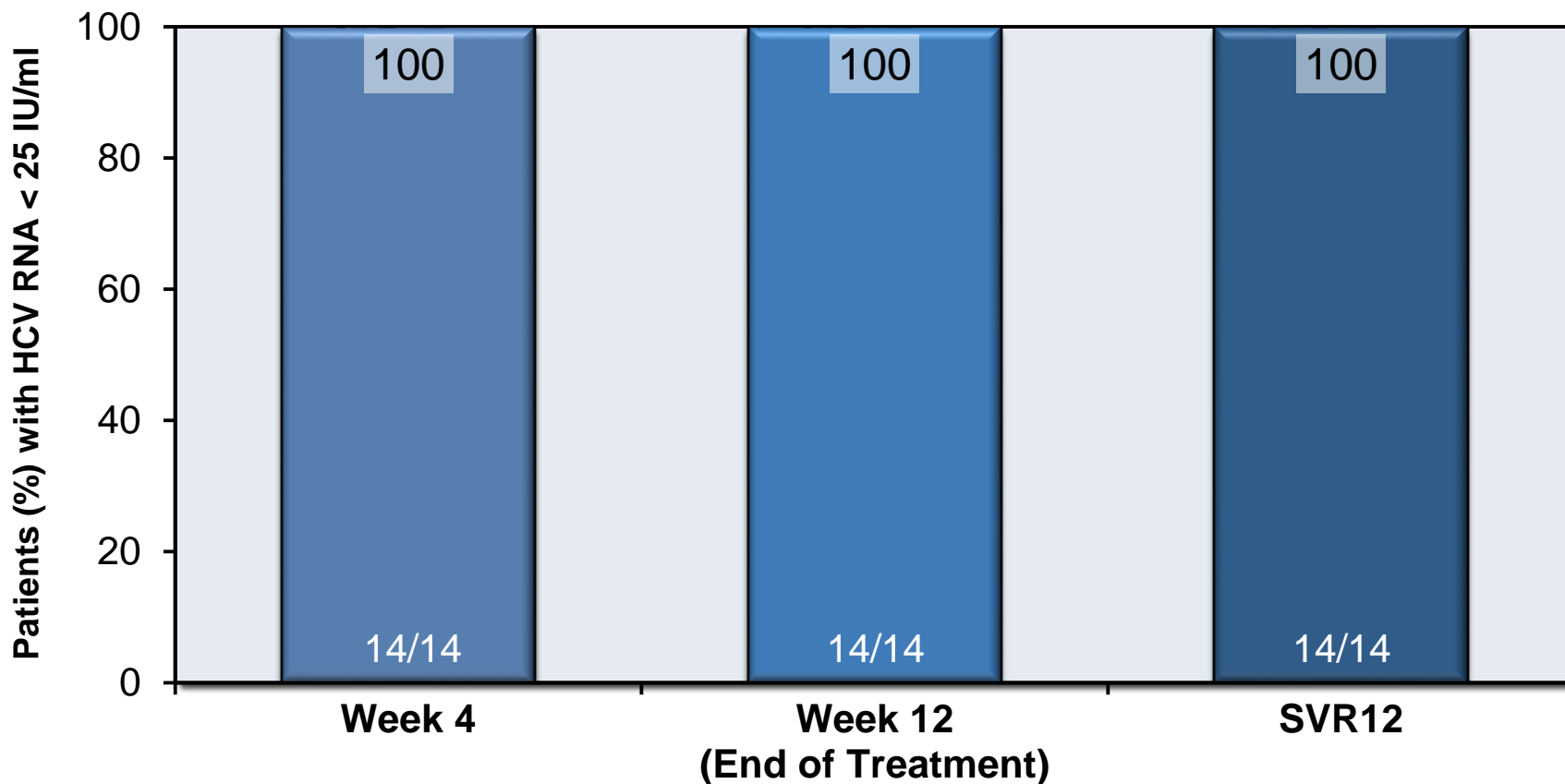
Ledipasvir-sofosbuvir (90/400 mg): fixed dose combination; one pill once daily

# 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) $\geq 30$ kg/m <sup>2</sup> , 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 <sub>10</sub> 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](http://www.hepatitisc.uw.edu)

Hepatitis Web Study

<http://depts.washington.edu/hepstudy/>

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