Sofosbuvir-Velpatasvir in Genotype 2
ASTRAL-2*

*Published in tandem with ASTRAL-3 Trial

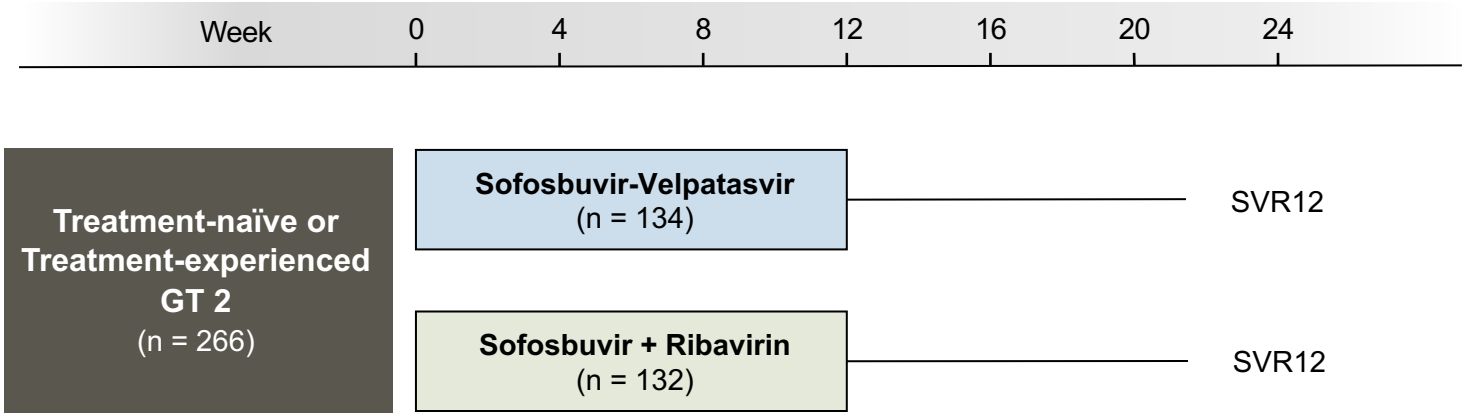
Source: Foster GR, et al. N Engl J Med. 2015;373:2608-17.

Sofosbuvir-Velpatasvir in HCV Genotype 2
ASTRAL-2: Study Features

- **Design**: Randomized, placebo-controlled, open-label, phase 3 trial using a fixed-dose combination of sofosbuvir-velpatasvir for 12 weeks compared with sofosbuvir plus ribavirin in treatment-naïve and treatment-experienced patients with GT 2 chronic HCV
- **Setting**: 51 sites in United States
- **Entry Criteria**
  - Chronic HCV GT 2
  - HCV RNA ≥10,000 IU/mL at screening
  - Prior treatment failure with interferon allowed (but no prior NS5A or NS5B)
  - Patients with compensated cirrhosis allowed
- **Primary End Point**: SVR12

Source: Foster GR, et al. N Engl J Med. 2015;373:2608-17.

Sofosbuvir-Velpatasvir in HCV Genotype 2
ASTRAL-2: Study Design



*Randomization stratified by treatment experience and cirrhosis status.

Drug Dosing
Sofosbuvir-velpatasvir (400/100 mg): fixed-dose combination; one pill once daily
Sofosbuvir: 400 mg once daily
Ribavirin (weight-based and divided bid): 1000 mg/day if <75 kg or 1200 mg/day if ≥75 kg

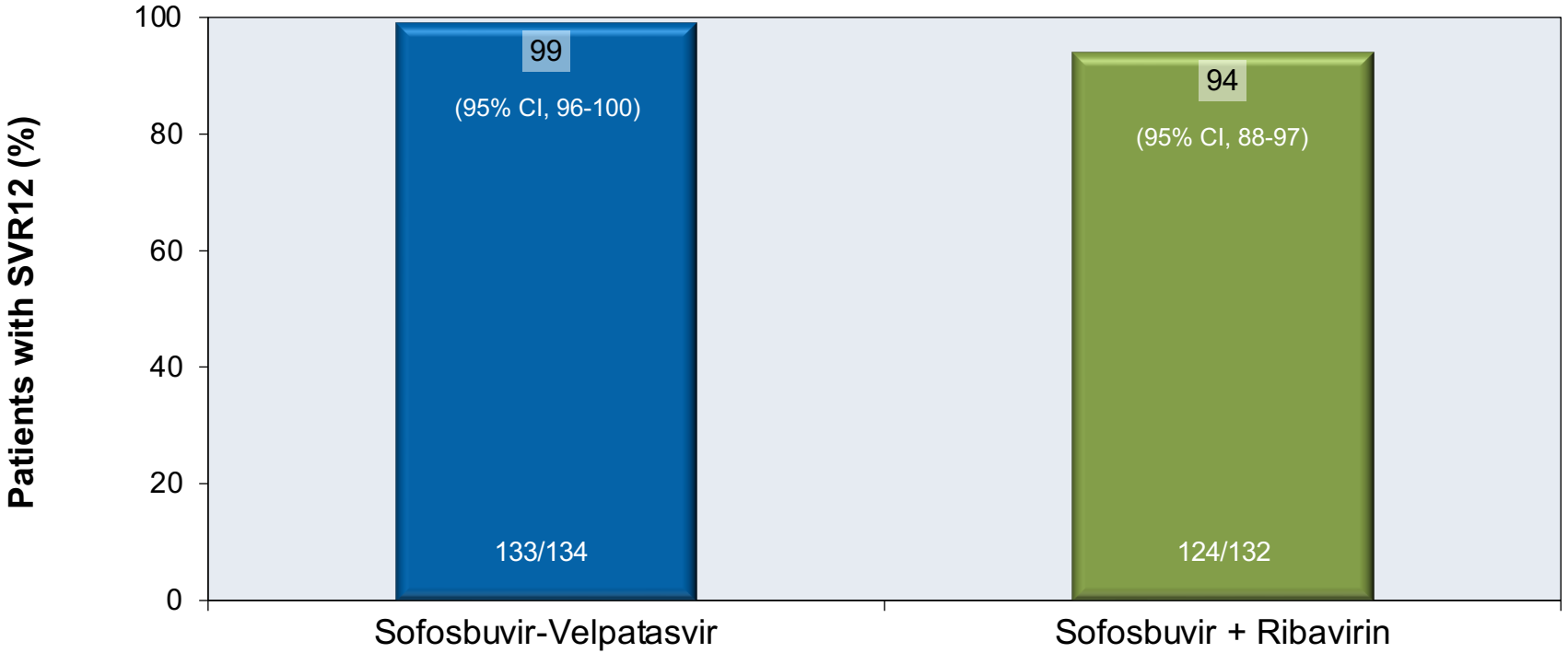
Source: Foster GR, et al. N Engl J Med. 2015;373:2608-17.

Sofosbuvir-Velpatasvir in HCV Genotype 2
ASTRAL-2: Baseline Characteristics

Baseline Characteristics	Sofosbuvir-Velpatasvir (n = 134)	Sofosbuvir + Ribavirin (n = 132)
Age, mean (range)	57 (26-81)	57 (23-76)
Male, n (%)	86 (64)	72 (55)
Race, n (%) White Black Asian	 124 (93) 6 (4) 1 (1)	 111 (84) 12 (9) 5 (4)
Body mass index, mean (range)	28 (17-45)	29 (19-61)
HCV RNA ≥800,000 IU/mL, n (%)	111 (83)	101 (77)
IL28B non-CC, n (%)	79 (59)	86 (65)
Cirrhosis, n (%)	19 (14)	19 (14)
Treatment-experienced, n (%)	19 (14)	20 (15)
Prior response, n/total (%) Non-response Relapse or breakthrough	 3/19 (16) 16/19 (84)	 3/20 (15) 17/20 (85)

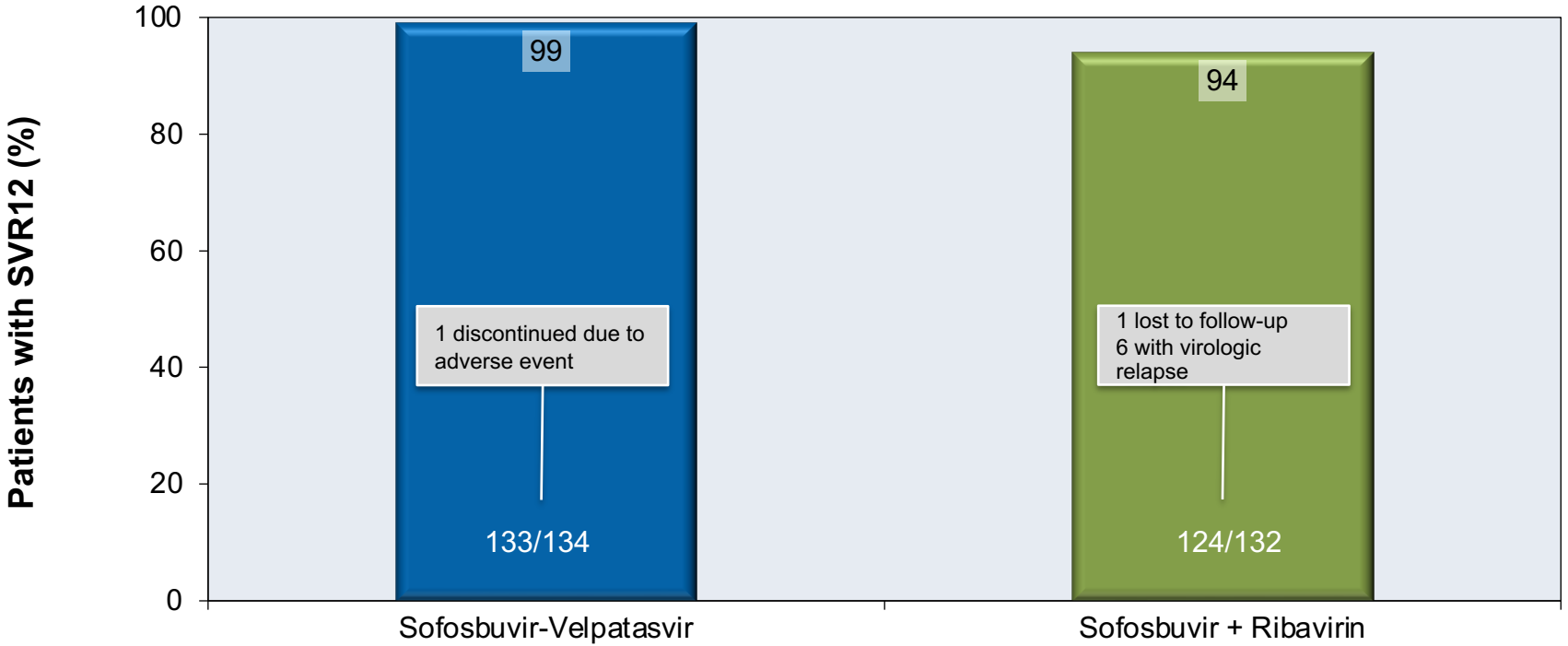
Source: Foster GR, et al. N Engl J Med. 2015;373:2608-17.

Sofosbuvir-Velpatasvir in HCV Genotype 2
ASTRAL-2: Results



Source: Foster GR, et al. N Engl J Med. 2015;373:2608-17.

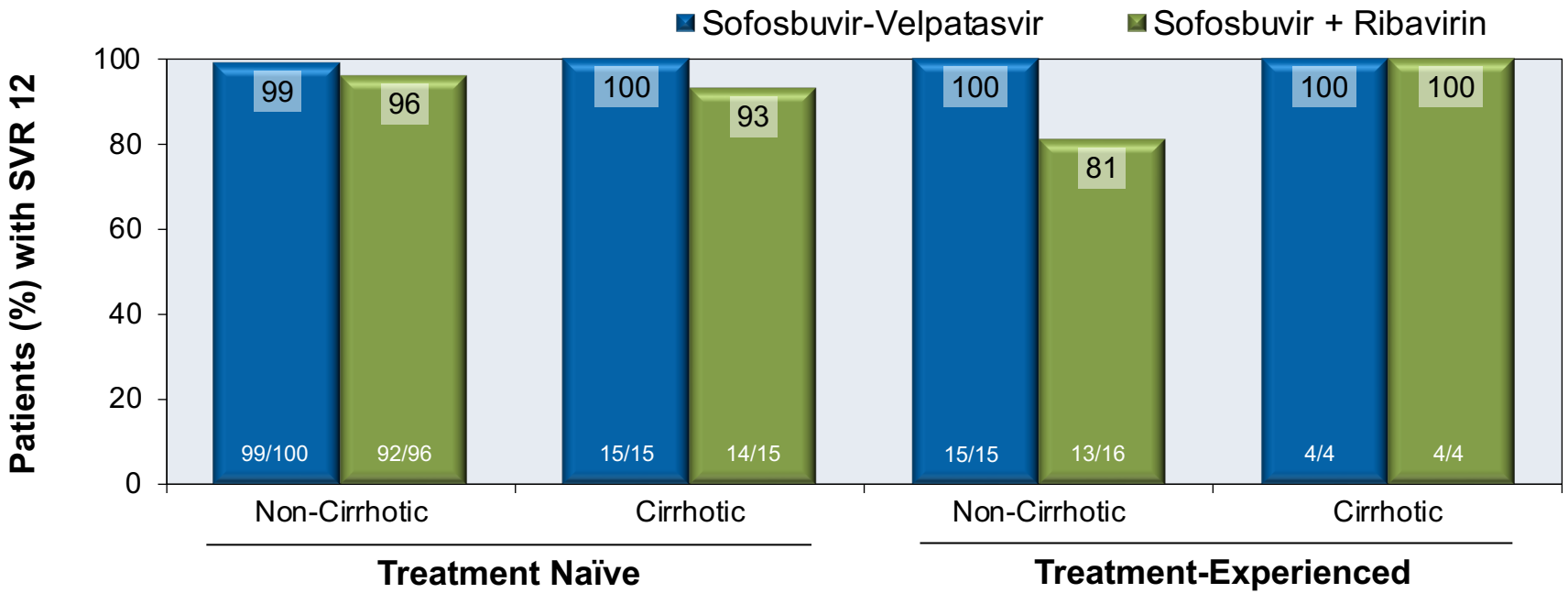
Sofosbuvir-Velpatasvir in HCV Genotype 2
ASTRAL-2: Results



Source: Foster GR, et al. N Engl J Med. 2015;373:2608-17.

Sofosbuvir-Velpatasvir in HCV Genotype 2
ASTRAL-2: Results

SVR12 Results by Treatment Experience and Cirrhosis Status



Source: Foster GR, et al. N Engl J Med. 2015;373:2608-17.

Sofosbuvir-Velpatasvir in HCV Genotype 2
ASTRAL-2: Adverse Events

Adverse Event (AE), n (%)	Sofosbuvir-Velpatasvir (n = 134)	Sofosbuvir + Ribavirin (n = 132)
Discontinuation due to AE	1 (1)	0
Serious AEs	2 (1)	2 (2)
Deaths	2[§] (1)	0
Any AE in ≥10% of patients		
Fatigue	20 (15)	47 (36)
Headache	24 (18)	29 (22)
Nausea	14 (10)	19 (14)
Insomnia	6 (4)	18 (14)
Laboratory AEs		
Hemoglobin <10 g/dl	0	6 (5)
Total bilirubin >2.5 to 3 mg/dL	0	3 (2)
Platelet count 25K to <50K/mm^3	0	0

[§] Deaths were not considered to be study-related.

Source: Foster GR, et al. N Engl J Med. 2015;373:2608-17.

Sofosbuvir-Velpatasvir in HCV Genotype 2
ASTRAL-2: Conclusions

Conclusions: “Among patients with HCV genotype 2 [or 3] with or without previous treatment, including those with compensated cirrhosis, 12 weeks of treatment with sofosbuvir-velpatasvir resulted in rates of sustained virologic response that were superior to those with standard treatment with sofosbuvir-ribavirin.”

Source: Foster GR, et al. N Engl J Med. 2015;373:2608-17.

Acknowledgments

Hepatitis C Online is funded by a cooperative agreement from the Centers for Disease Control and Prevention (CDC-RFA- PS21-2105). This project is led by the University of Washington Infectious Diseases Education and Assessment (IDEA) Program.

HEPATITIS B ONLINE

HEPATITIS C ONLINE

IDEA INFECTIOUS DISEASES EDUCATION & ASSESSMENT