

Treatment Naïve & Experienced

Sofosbuvir-Velpatasvir in Genotype 2 ASTRAL-2*

*Published in tandem with ASTRAL-3 Trial

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

Sofosbuvir-Velpatasvir in HCV Genotype 2

ASTRAL-2: Study Features

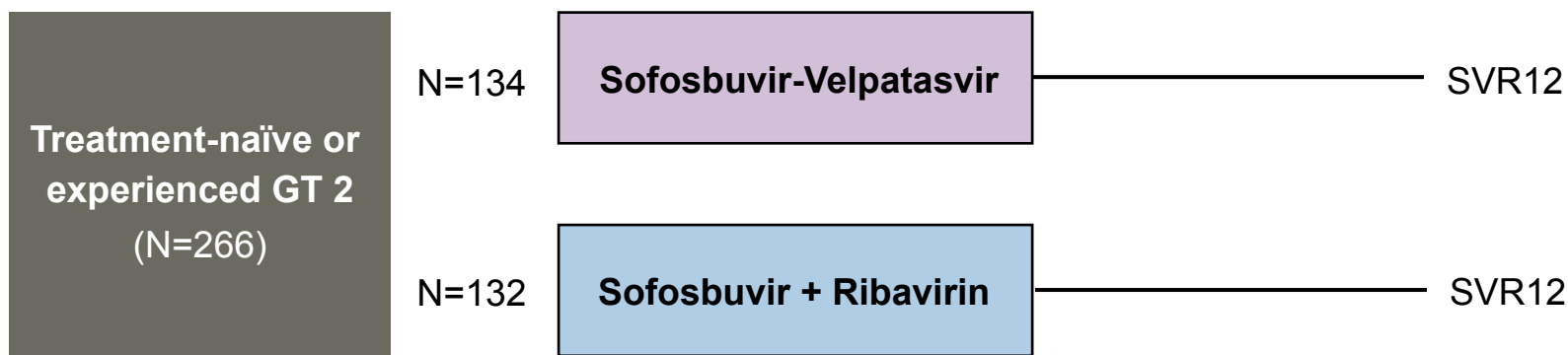
ASTRAL-2 Trial

- **Design:** Randomized, placebo-controlled, 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 $\geq 10,000$ 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

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ASTRAL-2: Study Design

Week 0 12 24



*Randomization stratified by treatment experience and cirrhosis status.

Abbreviations: SOF-VEL = sofosbuvir-velpatasvir; RBV = ribavirin

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

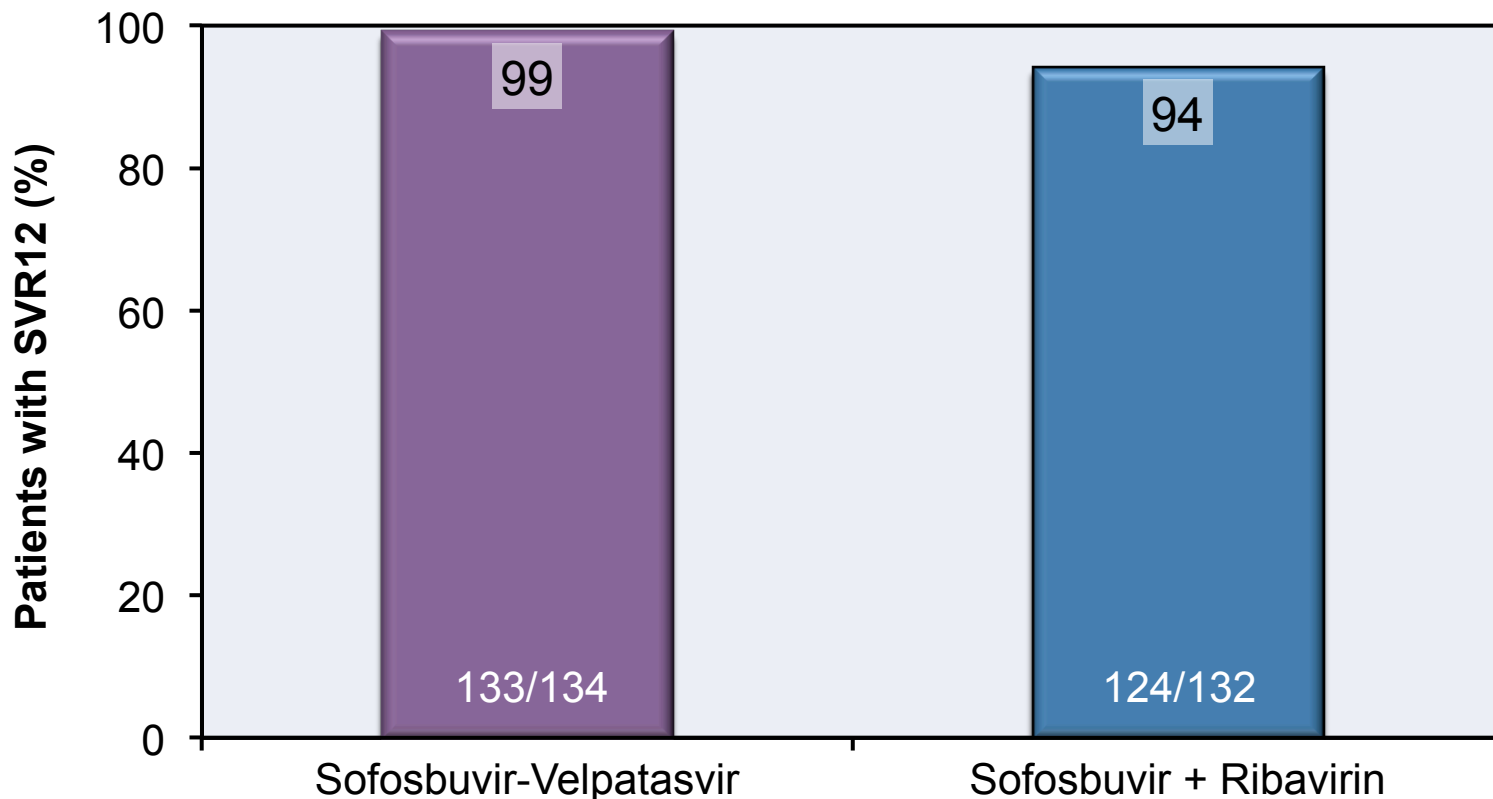
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ASTRAL-2: Baseline Characteristics

Baseline Characteristic	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	124 (93)	111 (84)
Black	6 (4)	12 (9)
Asian	1 (1)	5 (4)
Body mass index, mean (range)	28 (17-45)	29 (19-61)
HCV RNA \geq 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, no./total (%)		
Non-response	3/19 (16)	3/20 (15)
Relapse or breakthrough	16/19 (84)	17/20 (85)

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

ASTRAL-2: SVR12 Results

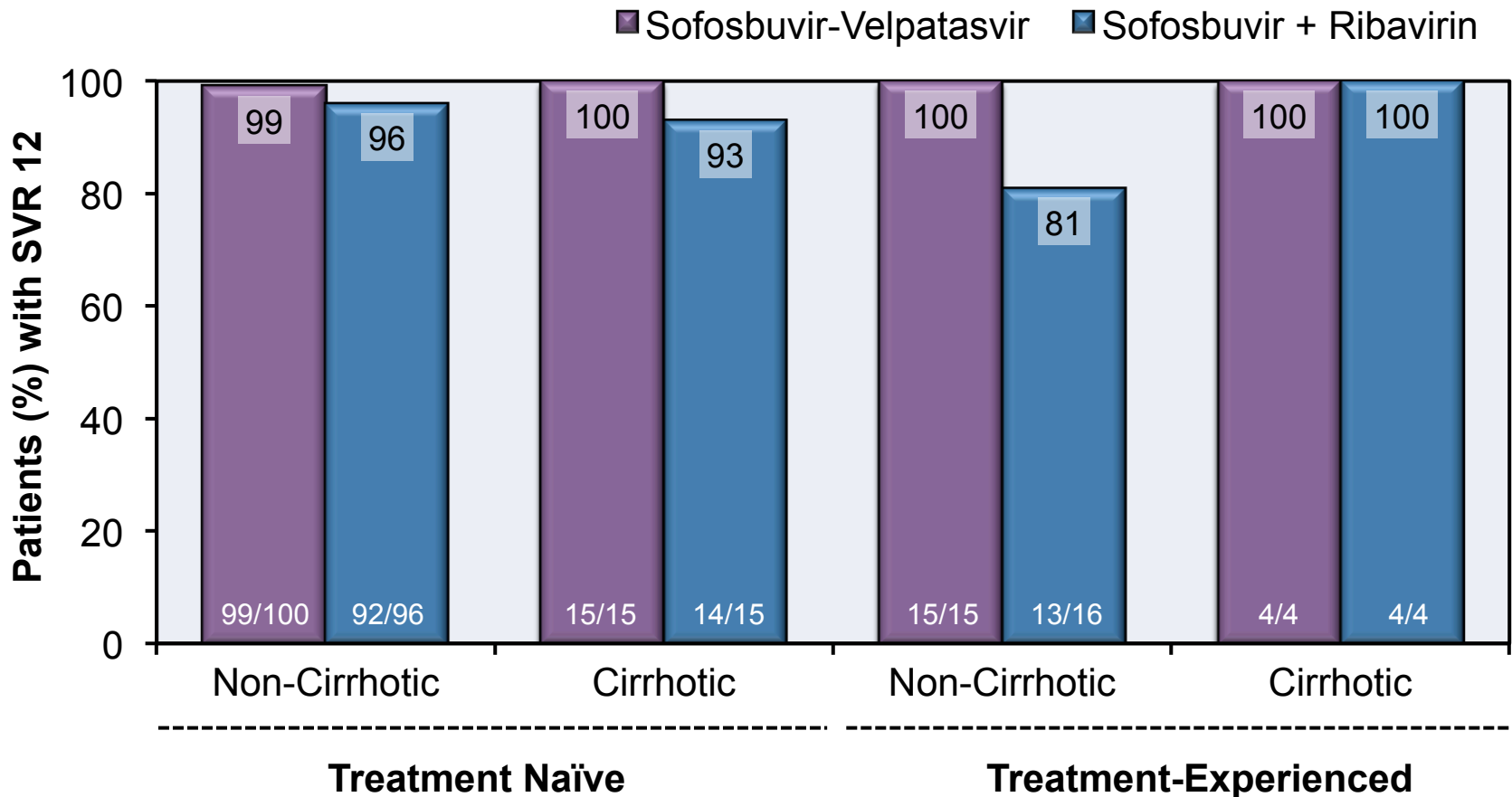


P=0.018 for superiority of Sofosbuvir-Velpatasvir compared with Sofosbuvir + Ribavirin

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

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

ASTRAL-2: SVR12 Results by Cirrhosis & Treatment Experience



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.

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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.”