

HEPATITIS WEB STUDY  HEPATITIS C ONLINE

# Sofosbuvir-Velpatasvir (*Epclusa*)

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Last Updated: August 16, 2017

SOFOSBUVIR-VELPATASVIR (*EPCLUSA*)  
Background and Dosing

# Sofosbuvir-Velpatasvir (*Epclusa*)

- **Approval Status**

- Approval by United States FDA on June 28, 2016

- **Indications and Usage**

- Indicated for the treatment of chronic HCV genotypes 1-6 in adults:

- without cirrhosis or with compensated cirrhosis (Child-Pugh A)
    - with decompensated cirrhosis (Child-Pugh B and C) combined with ribavirin

- **Class and Mechanism**

- Sofosbuvir: HCV NS5B polymerase inhibitor
  - Velpatasvir: HCV NS5A inhibitor

- **Preparation:** Sofosbuvir-Velpatasvir (fixed dose 400 mg/100 mg)

- **Dosing:** One tablet orally once daily, with or without food

- **Adverse Effects (AE):** Headache and fatigue

# Sofosbuvir-Velpatasvir (*Epclusa*) Indications and Usage

## Sofosbuvir-Velpatasvir\* for HCV Treatment in Patients with Genotype 1-6

Patient Population	Treatment	Duration
Patients without cirrhosis and patients with compensated cirrhosis (Child-Pugh A)	Sofosbuvir-Velpatasvir	12 weeks
Patients with decompensated cirrhosis (Child-Pugh B and C)	Sofosbuvir-Velpatasvir + Ribavirin <sup>^</sup>	12 weeks

A dosage recommendation cannot be made for patients with severe renal impairment or end stage renal disease.

<sup>^</sup>The recommended dosage of ribavirin is based on weight (administered with food): 1000 mg per day for patients less than 75 kg and 1200 mg for those weighing at least 75 kg, divided and administered twice daily. The starting dosage and on-treatment dosage of ribavirin can be decreased based on hemoglobin and creatinine clearance. For ribavirin dosage modifications, refer to the ribavirin prescribing information.

# Sofosbuvir-Velpatasvir (*Epclusa*) Estimated Cost of Therapy

## Estimated Cost of Sofosbuvir-Velpatasvir Based on Treatment Duration

Duration of Treatment	Estimated Cost*
12 Weeks	\$74,760

\*Estimated cost based on Wholesaler Acquisition Cost in United States of \$890 per pill

Treatment Naïve & Experienced

# Sofosbuvir-Velpatasvir in HCV Genotype 1, 2, 4, 5, or 6 ASTRAL-1

Feld JJ, et al. N Engl J Med. 2015;373:2599-607.

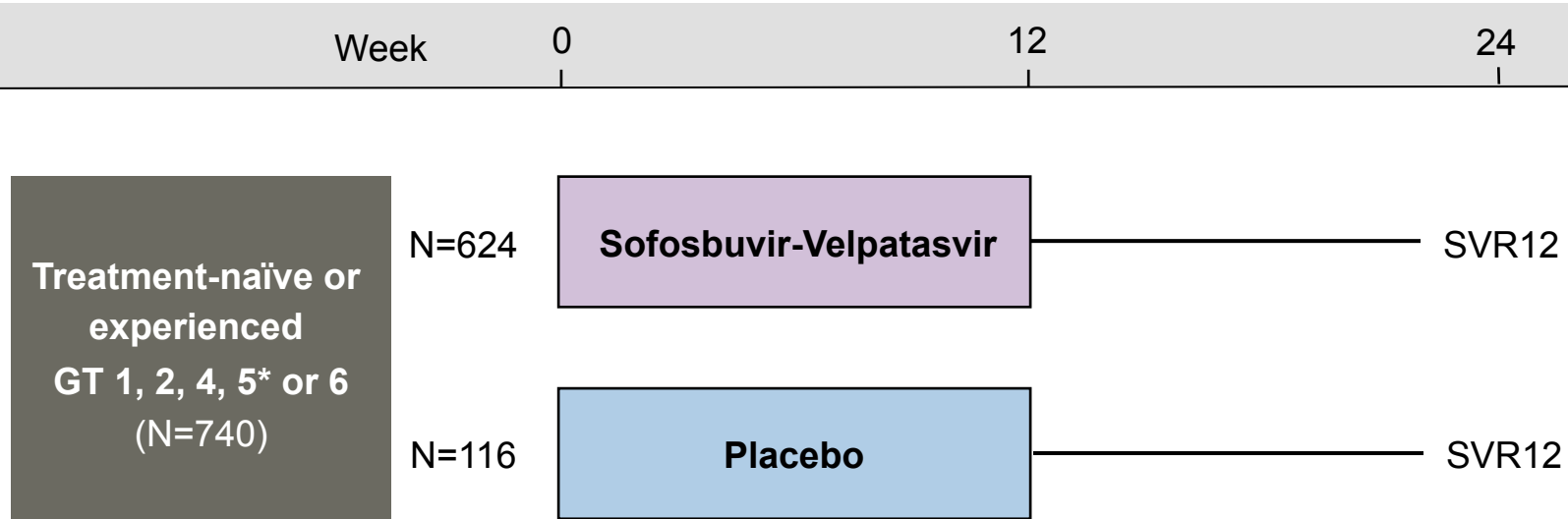
# Sofosbuvir-Velpatasvir in HCV Genotype 1, 2, 4, 5, or 6

## ASTRAL-1: Study Features

### ASTRAL-1 Trial

- **Design:** Randomized, placebo-controlled, phase 3 trial using a fixed-dose combination of sofosbuvir-velpatasvir for 12 weeks in treatment-naïve and treatment-experienced patients with GT 1, 2, 4, 5, or 6 chronic HCV
- **Setting:** 81 sites in United States, Europe, & Hong Kong
- **Entry Criteria**
  - Chronic HCV GT 1, 2, 4, 5, 6
  - 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

# Sofosbuvir-Velpatasvir in HCV Genotype 1, 2, 4, 5, or 6 ASTRAL-1: Study Design



Randomized 5:1 ratio for treatment to placebo. Stratified by cirrhosis and HCV genotype.

\*Genotype 5 patients (n=6) were assigned to active arm (and not randomized)

Placebo recipients were eligible for deferred treatment with sofosbuvir-velpatasvir

## Drug Dosing

Sofosbuvir-Velpatasvir (400/100 mg): fixed dose combination; one pill once daily

# Sofosbuvir-Velpatasvir in HCV Genotype 1, 2, 4, 5, or 6 ASTRAL-1: Baseline Characteristics

Baseline Characteristic	Sofosbuvir-Velpatasvir (N=624)	Placebo (N=113)
Age, mean (range)	54 (18-82)	53 (25-74)
Male, n (%)	374 (60)	68 (59)
Race, n (%)		
White	493 (79)	90 (78)
Black	52 (8)	11 (9)
Asian	62 (10)	11 (9)
HCV genotype, %		
1a	210 (34)	46 (40)
1b	118 (19)	19 (16)
2	104 (17)	21 (18)
4	116 (19)	22 (19)
5	35 (6)	0
6	41 (7)	8 (7)
Body mass index, mean (range)	27 (17-57)	26 (18-40)
HCV RNA $\geq$ 800,000 IU/mL, n (%)	461 (74)	87 (75)
IL28B non-CC, n (%)	433 (69)	79 (68)

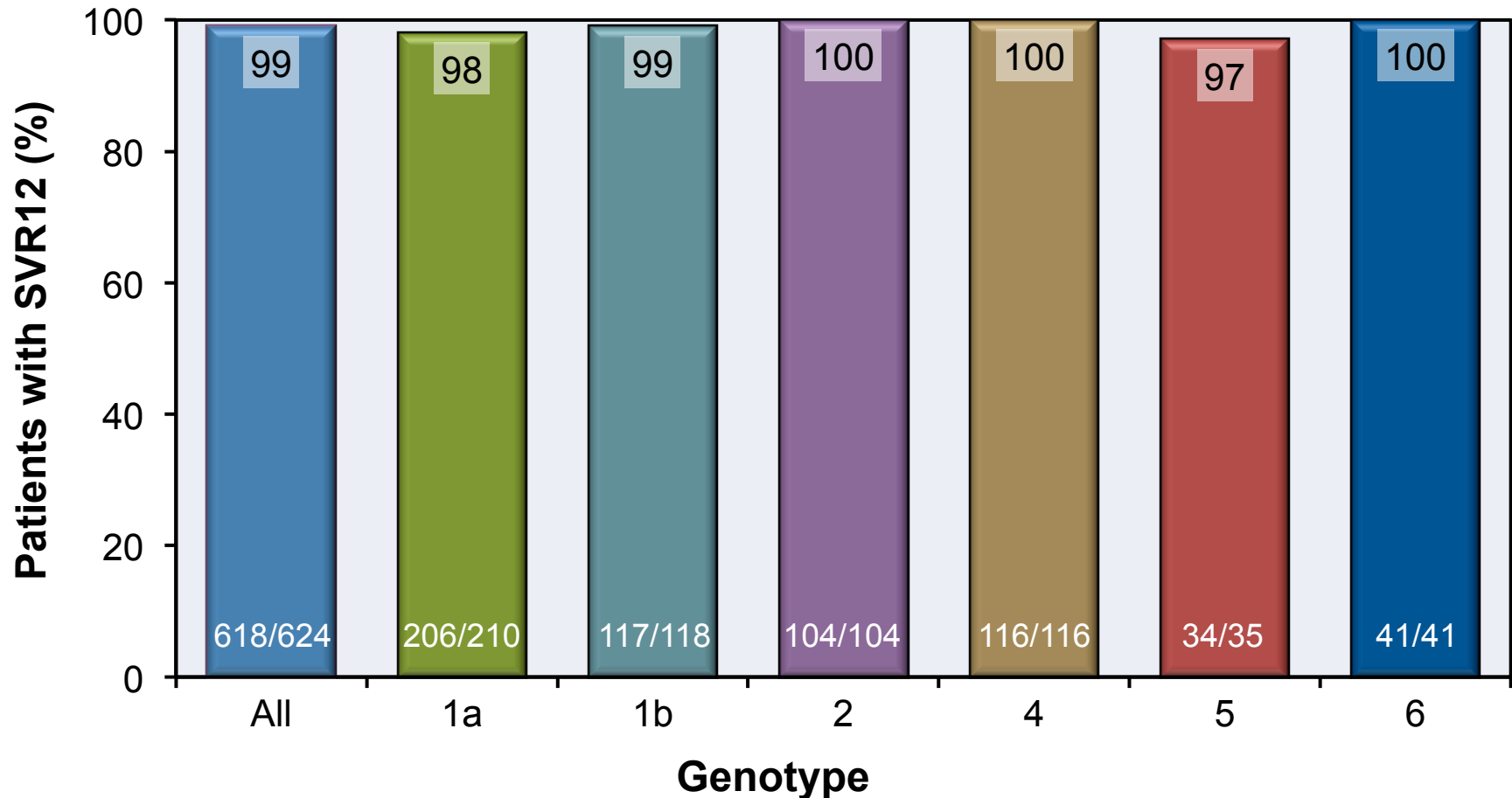
Source: Feld JJ, et al. N Engl J Med. 2015;373:2599-607.

# Sofosbuvir-Velpatasvir in HCV Genotype 1, 2, 4, 5, or 6 ASTRAL-1: Baseline Characteristics

Baseline Characteristic	Sofosbuvir-Velpatasvir (N=624)	Placebo (N=113)
Cirrhosis, n (%)	121 (19)	21 (18)
Treatment experienced, n (%)	201 (32)	33 (28)
Prior therapy, n (%)		
Peginterferon + Ribavirin	122 (61)	24 (73)
Peginterferon + Ribavirin + Protease Inhibitor	56 (28)	6 (18)
Standard Interferon +/- Ribavirin	23 (11)	3 (9)

# Sofosbuvir-Velpatasvir in HCV Genotype 1, 2, 4, 5, or 6 ASTRAL-1: Results

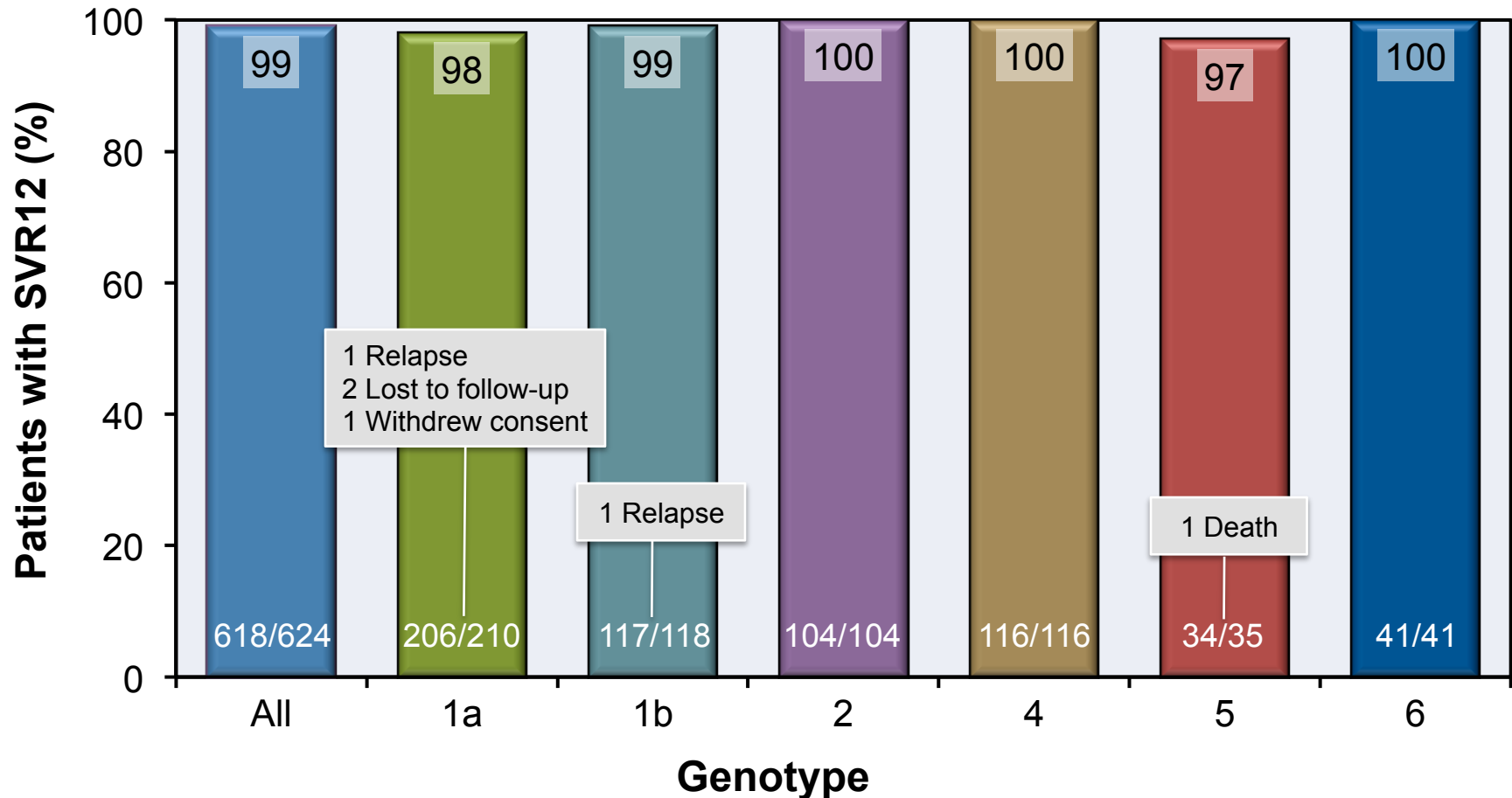
## ASTRAL-1: SVR12 Results by Genotype



Source: Feld JJ, et al. N Engl J Med. 2015;373:2599-607.

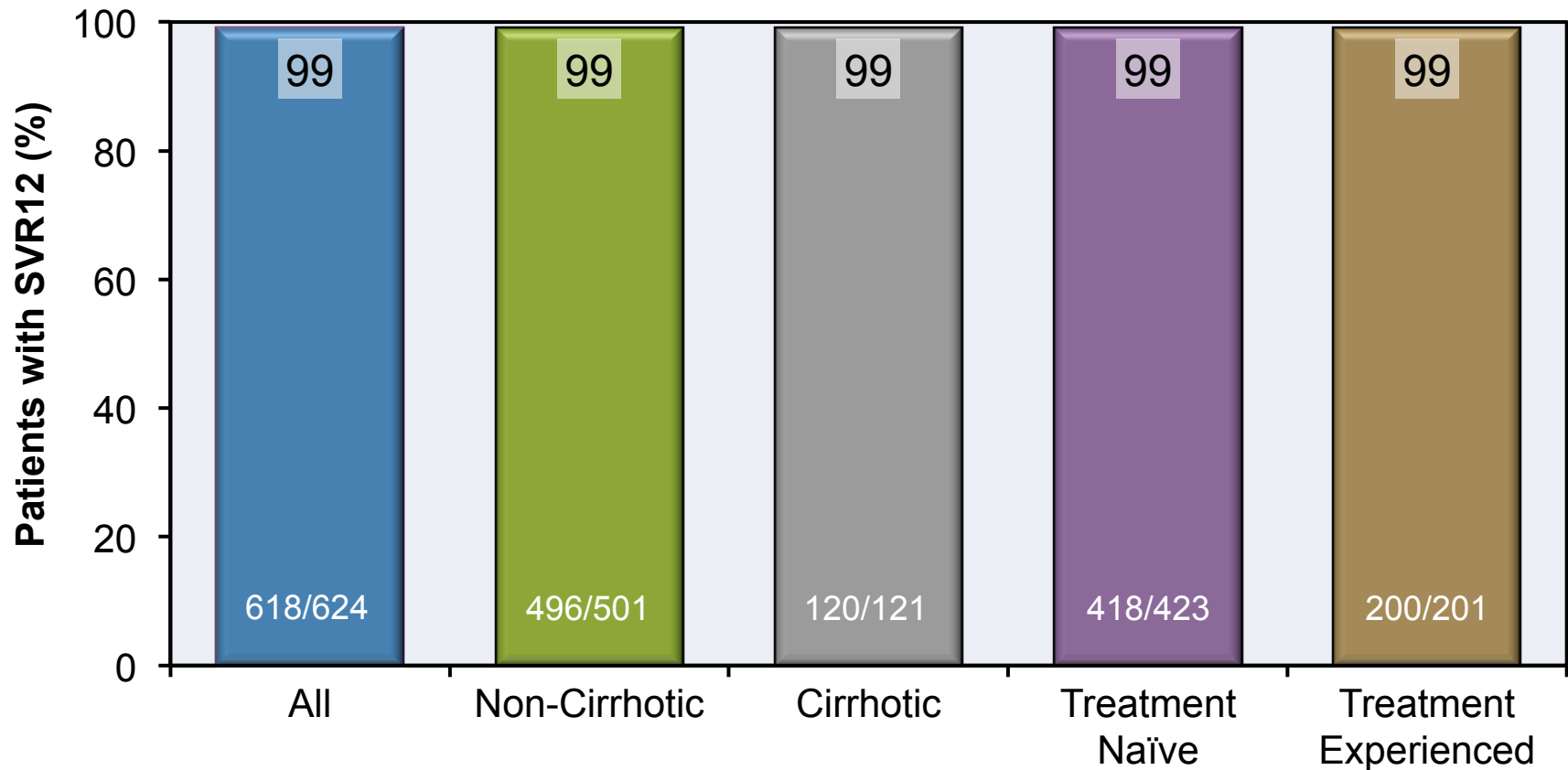
# Sofosbuvir-Velpatasvir in HCV Genotype 1, 2, 4, 5, or 6 ASTRAL-1: Results

## ASTRAL-1: SVR12 Results by Genotype



# Sofosbuvir-Velpatasvir in HCV Genotype 1, 2, 4, 5, or 6 ASTRAL-1: Results

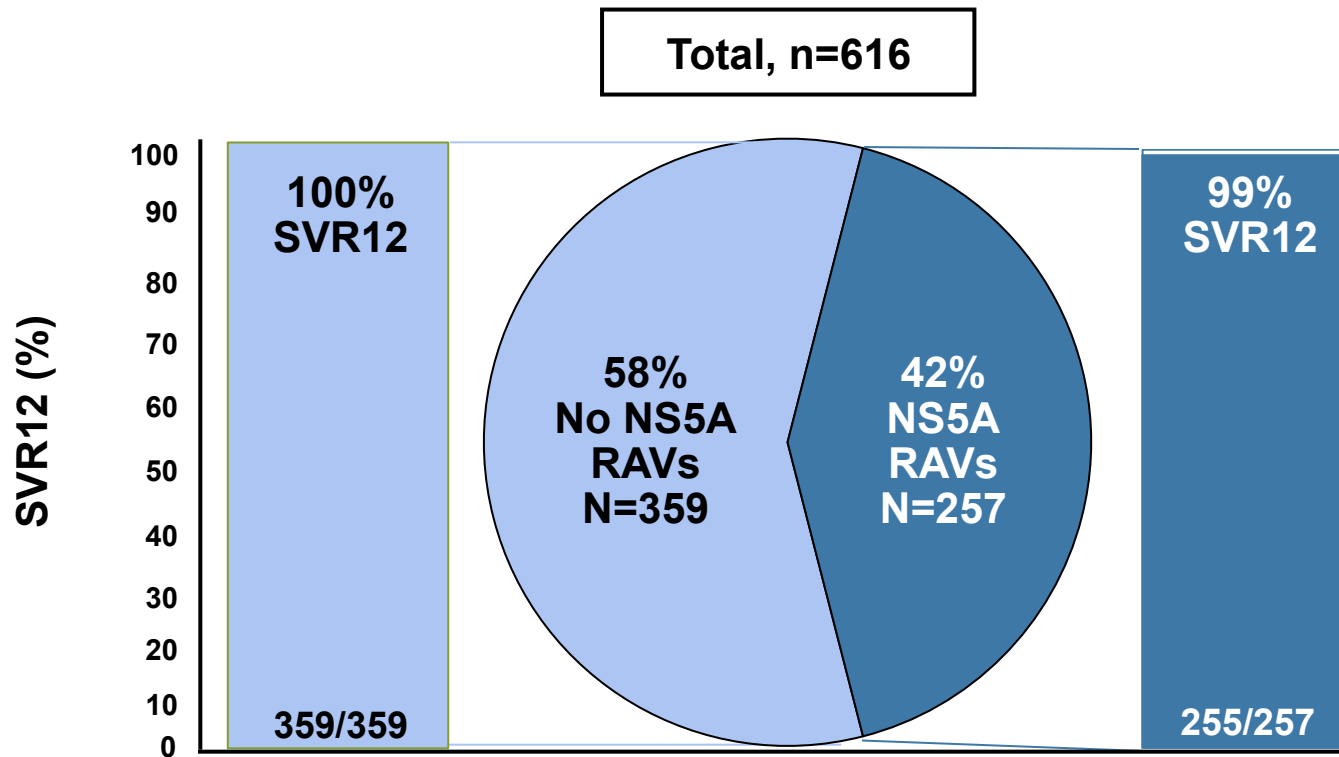
## ASTRAL-1: SVR12 Results by Cirrhosis & Treatment Experience



Source: Feld JJ, et al. N Engl J Med. 2015;373:2599-607.

# Sofosbuvir-Velpatasvir in HCV Genotype 1, 2, 4, 5, or 6 ASTRAL-1: Resistance

## Baseline NS5A Resistance-Associated Variants and SVR12



# Sofosbuvir-Velpatasvir in HCV Genotype 1, 2, 4, 5, or 6 ASTRAL-1: Adverse Events

Adverse Event (AE), n (%)	SOF-VEL (n=624)	Placebo (n=116)
Discontinuation due to AE	1 (<1)	2 (2)
Serious AEs	15 (2)	0
Deaths	1 <sup>§</sup> (<1)	0
Any AE in ≥10% of patients		
Headache	182 (29)	33 (28)
Fatigue	126 (20)	23 (20)
Nasopharyngitis	79 (13)	12 (10)
Nausea	75 (12)	13 (11)
Laboratory AEs		
Hemoglobin <10 g/dl	2 (<1)	0
Lymphocyte count 350 to <500/mm <sup>3</sup>	3 (<1)	0
Neutrophil count 500 to <750/mm <sup>3</sup>	4 (1)	0
Platelet count 25K to <50K/mm <sup>3</sup>	1 (<1)	0

<sup>§</sup> Death was not considered to be study-related.

# Sofosbuvir-Velpatasvir in HCV Genotype 1, 2, 4, 5, or 6 ASTRAL-1: Conclusion

**Conclusions:** “Once-daily sofosbuvir–velpatasvir for 12 weeks provided high rates of sustained virologic response among both previously treated and untreated patients infected with HCV genotype 1, 2, 4, 5, or 6, including those with compensated cirrhosis.”

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

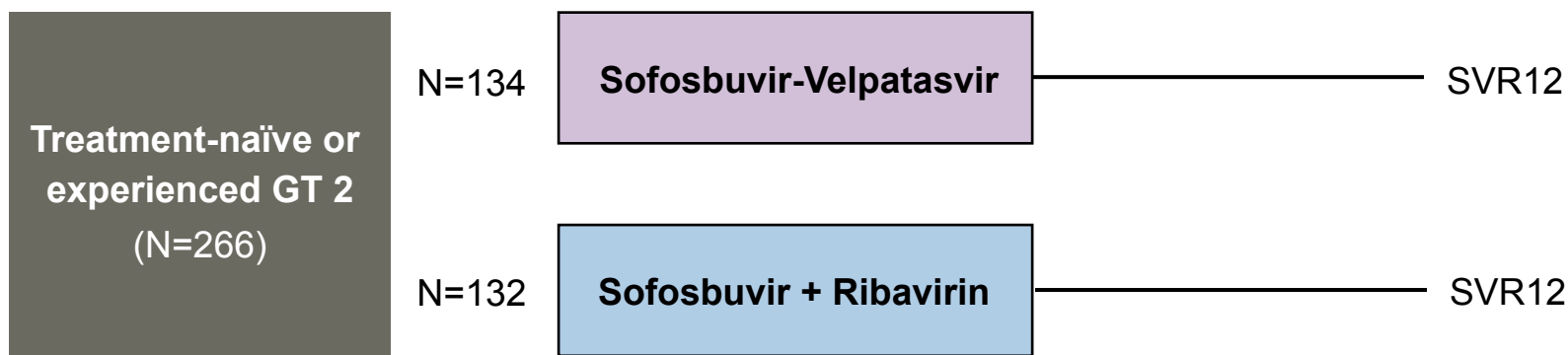
## ASTRAL-2: Study Features

### 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

# Sofosbuvir-Velpatasvir in HCV Genotype 2 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

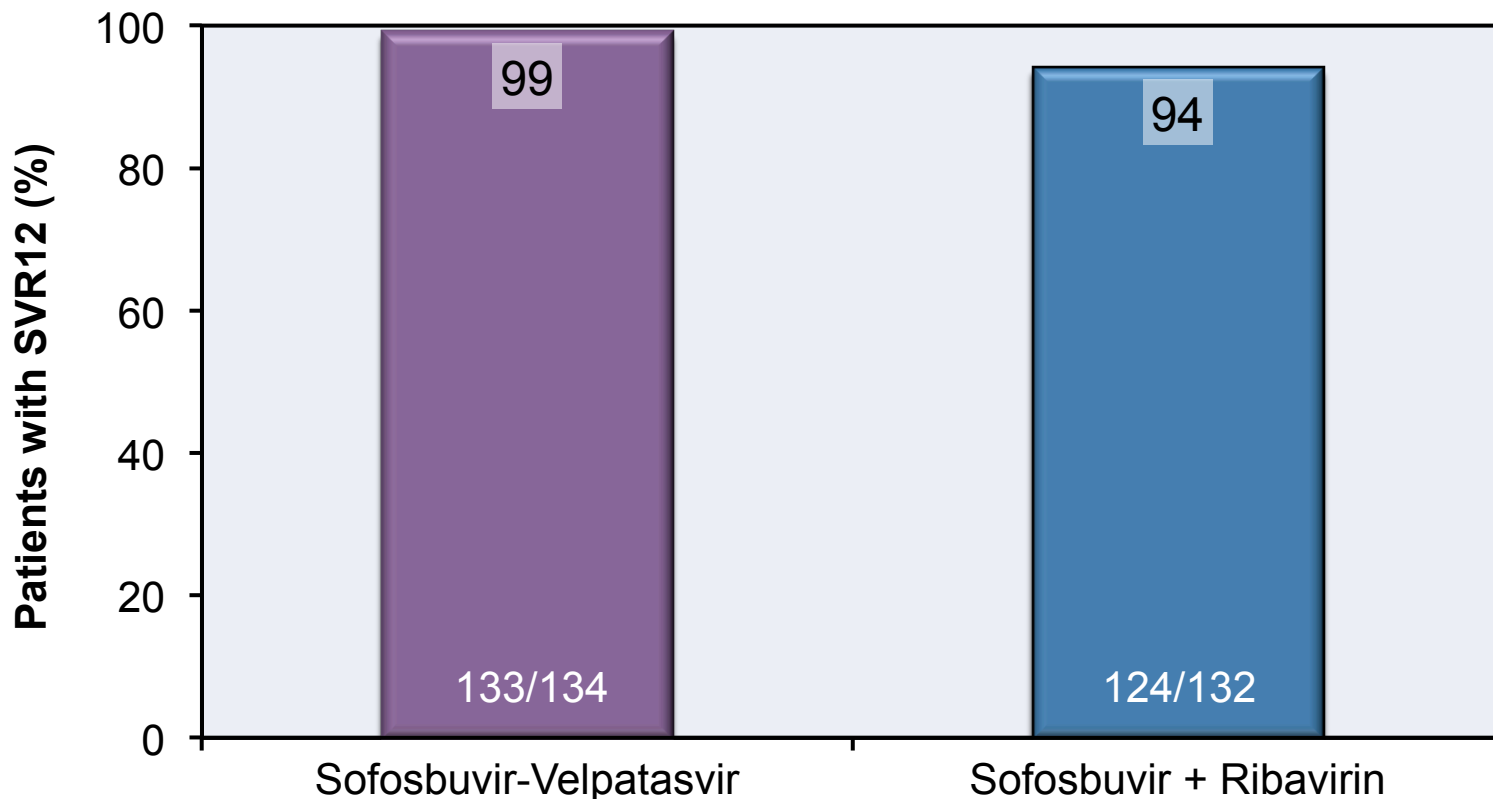
# Sofosbuvir-Velpatasvir in HCV Genotype 2

## 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

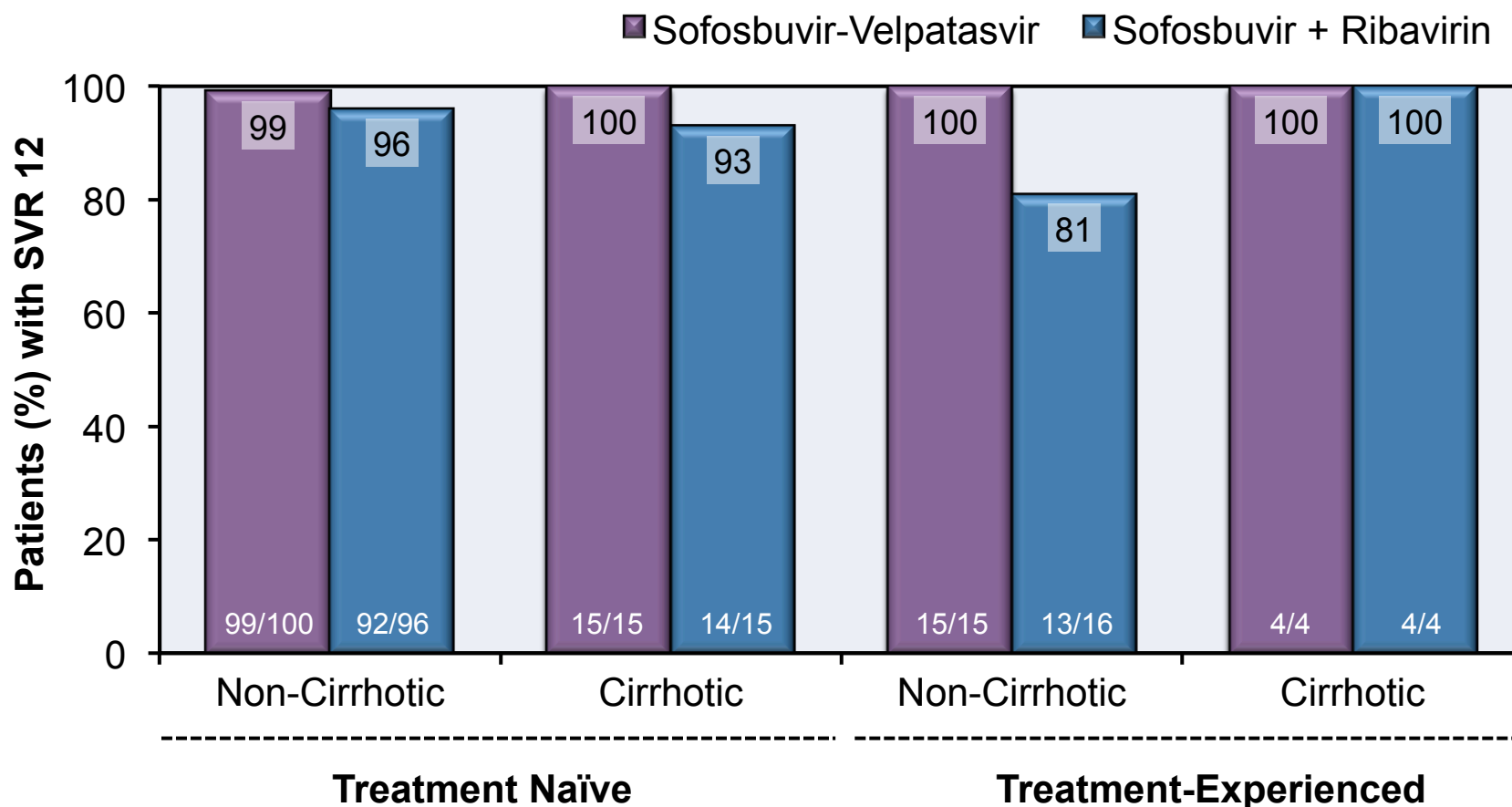


P=0.018 for superiority of Sofosbuvir-Velpatasvir compared with Sofosbuvir + Ribavirin

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 <sup>§</sup> (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 <sup>3</sup>	0	0

§ Deaths were not considered to be study-related.

# 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.”

Treatment Naïve & Experienced

# Sofosbuvir-Velpatasvir in Genotype 3 ASTRAL-3

\*Published in tandem with ASTRAL-2 Trial

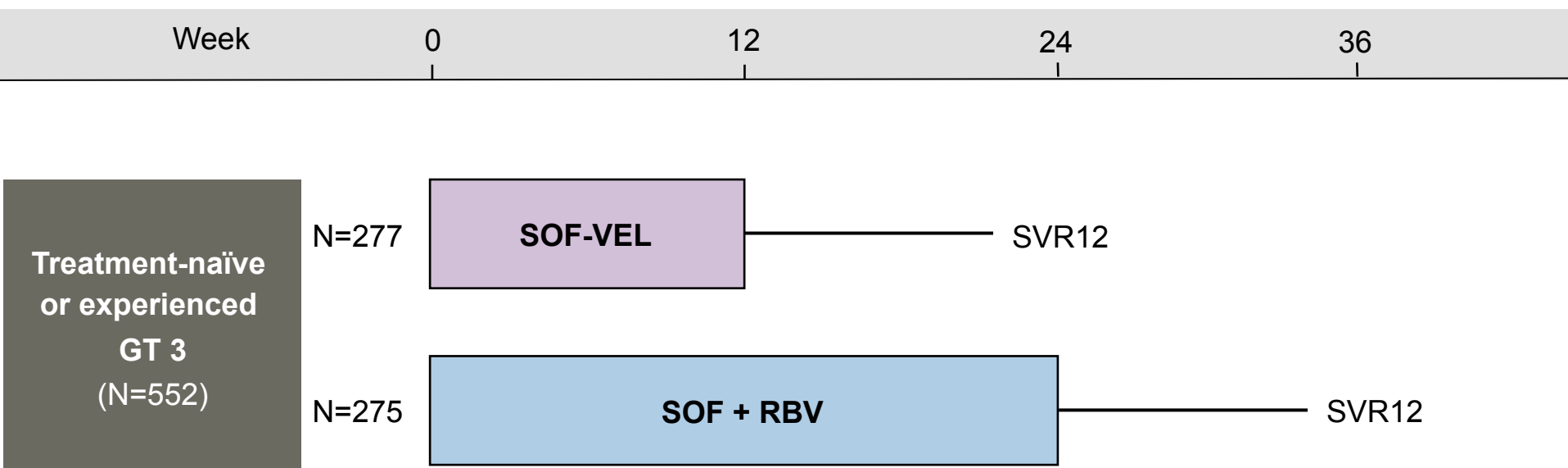
Foster GR, et al. N Engl J Med. 2015;373:2608-17.

# Sofosbuvir-Velpatasvir in HCV Genotype 3 ASTRAL-3: Study Features

## ASTRAL-3 Trial

- **Design:** Randomized, placebo-controlled, phase 3 trial using a fixed-dose combination of sofosbuvir-velpatasvir for 12 weeks (compared with sofosbuvir + ribavirin) in treatment-naïve and treatment-experienced patients with GT 3 chronic HCV
- **Setting:** 76 sites in US, Canada, Europe, Australia, New Zealand
- **Entry Criteria**
  - Chronic HCV GT 3
  - 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

# Sofosbuvir-Velpatasvir in HCV Genotype 3 ASTRAL-3: Study Design



\*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

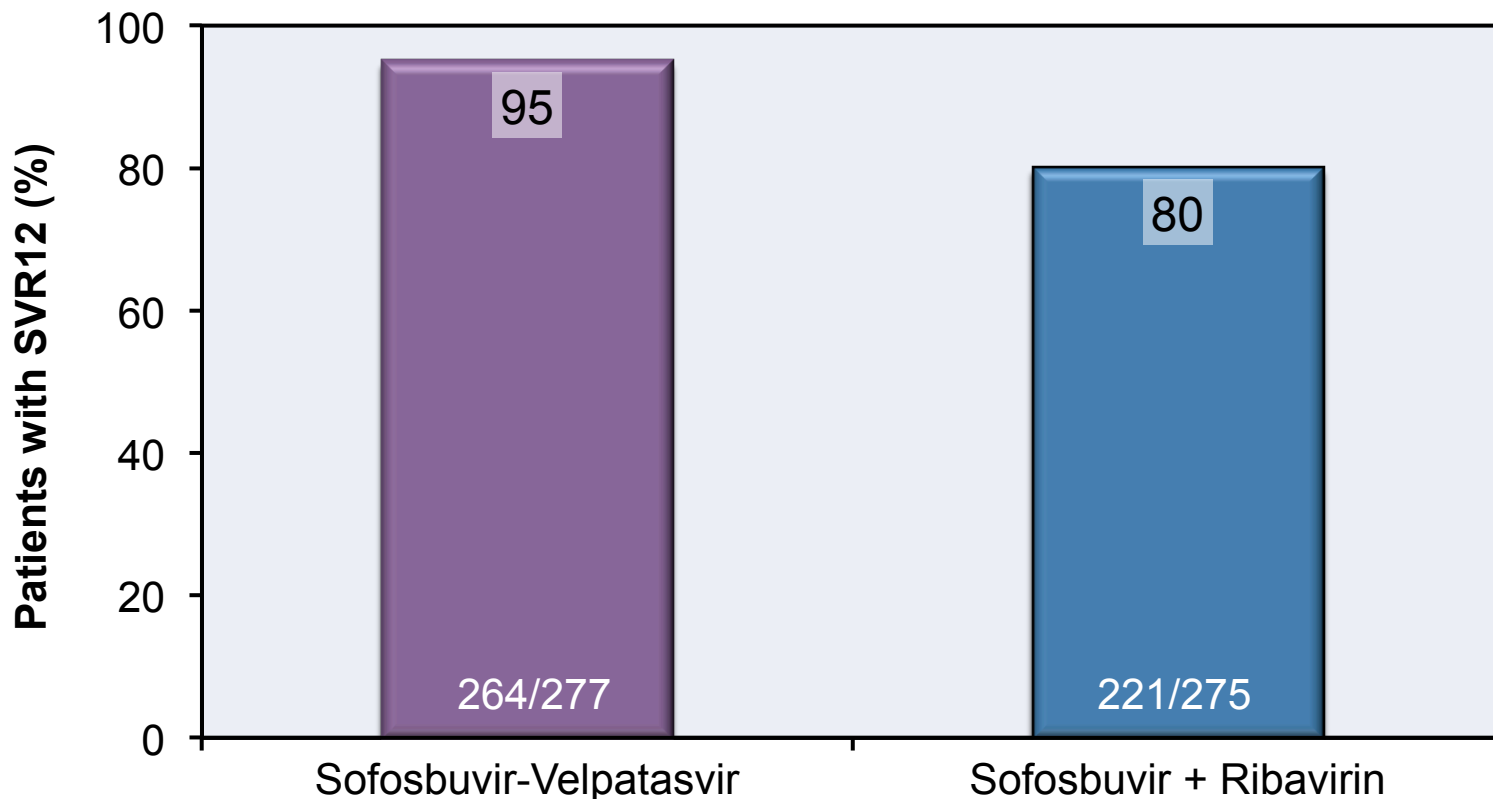
Ribavirin (weight-based and divided bid): 1000 mg/day if < 75 kg or 1200 mg/day if ≥ 75 kg

# Sofosbuvir-Velpatasvir in HCV Genotype 3 ASTRAL-3: Baseline Characteristics

Baseline Characteristic	Sofosbuvir-Velpatasvir (N=277)	Sofosbuvir + Ribavirin (N=275)
Age, mean (range)	49 (21-76)	50 (19-74)
Male, n (%)	170 (61)	174 (63)
Race, n (%)		
White	250 (90)	239 (87)
Black	3 (1)	1 (<1)
Asian	23 (8)	29 (11)
Body mass index, mean (range)	26 (17-48)	27 (17-56)
HCV RNA $\geq$ 800,000 IU/mL, n (%)	191 (69)	194 (71)
IL28B non-CC, n (%)	172 (62)	164 (60)
Cirrhosis, n (%)	80 (29)	83 (30)
Treatment-experienced, n (%)	71 (26)	71 (26)
Prior response, no./total (%)		
Non-response	20/71 (28)	24/71 (34)
Relapse or breakthrough	51/71 (72)	47/71 (66)

# Sofosbuvir-Velpatasvir in HCV Genotype 3 ASTRAL-3: Results

## ASTRAL-3: SVR12 Results

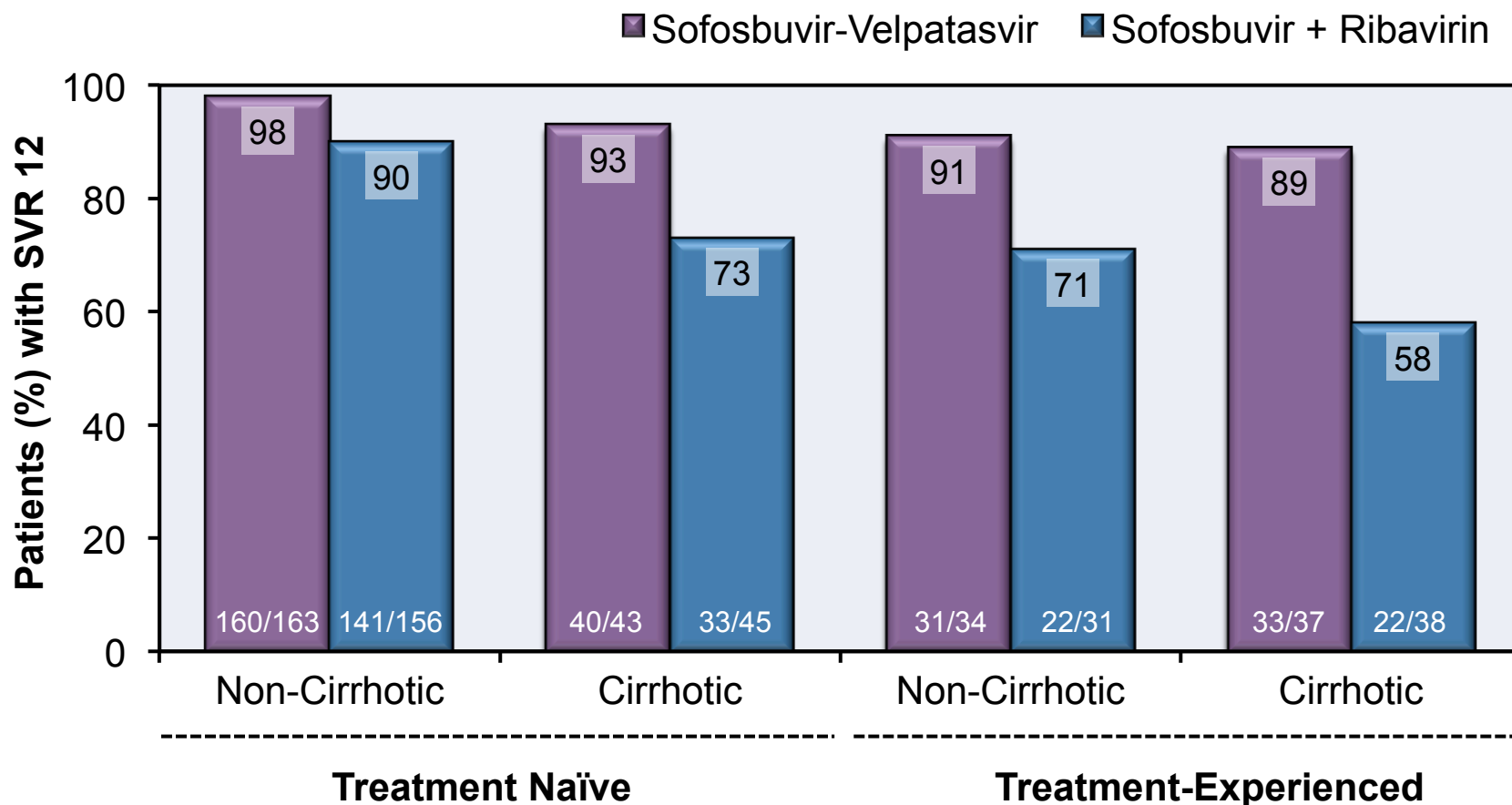


$P < 0.001$  for superiority of Sofosbuvir-Velpatasvir compared with Sofosbuvir + Ribavirin

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

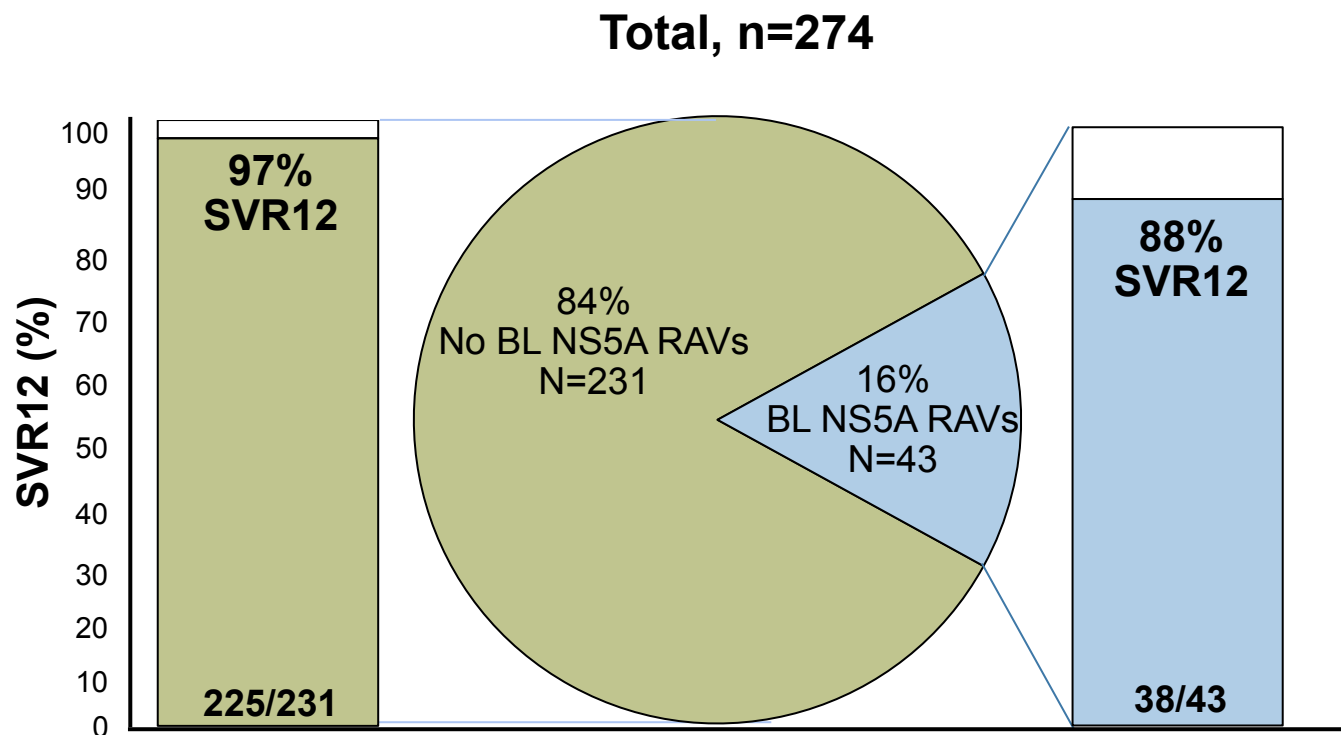
# Sofosbuvir-Velpatasvir in HCV Genotype 3 ASTRAL-3: Results

## ASTRAL-3: SVR12 Results by Cirrhosis & Treatment Experience



# Sofosbuvir-Velpatasvir in HCV Genotype 3 ASTRAL-3: Resistance

## Baseline NS5A Resistance-Associated Variants and SVR12



- SVR12 was 84% (21/25) in patients with Y93H

# Sofosbuvir-Velpatasvir in HCV Genotype 3 ASTRAL-3: Adverse Events

Adverse Event (AE), n (%)	Sofosbuvir-Velpatasvir (n=277)	Sofosbuvir + Ribavirin (n=275)
Discontinuation due to AE	0	9 (3)
Serious AEs	6 (2)	15 (5)
Deaths	0	3 (1)
Any AE in ≥10% of patients		
Fatigue	71 (26)	105 (38)
Headache	90 (32)	89 (32)
Nausea	46 (17)	58 (21)
Insomnia	31 (11)	74 (27)
Laboratory AEs		
Hemoglobin <10 g/dl	0	10 (4)
Total bilirubin >2.5 to 3 mg/dl	0	2 (1)
Platelet count 25K to <50K/mm <sup>3</sup>	1 (<1)	1 (<1)

# Sofosbuvir-Velpatasvir in HCV Genotype 3 ASTRAL-3: 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.”

Treatment Naïve & Experienced

# Sofosbuvir-Velpatasvir in Decompensated HCV Cirrhosis ASTRAL-4

Curry MP, et al. N Engl J Med. 2015;373:2618-28.

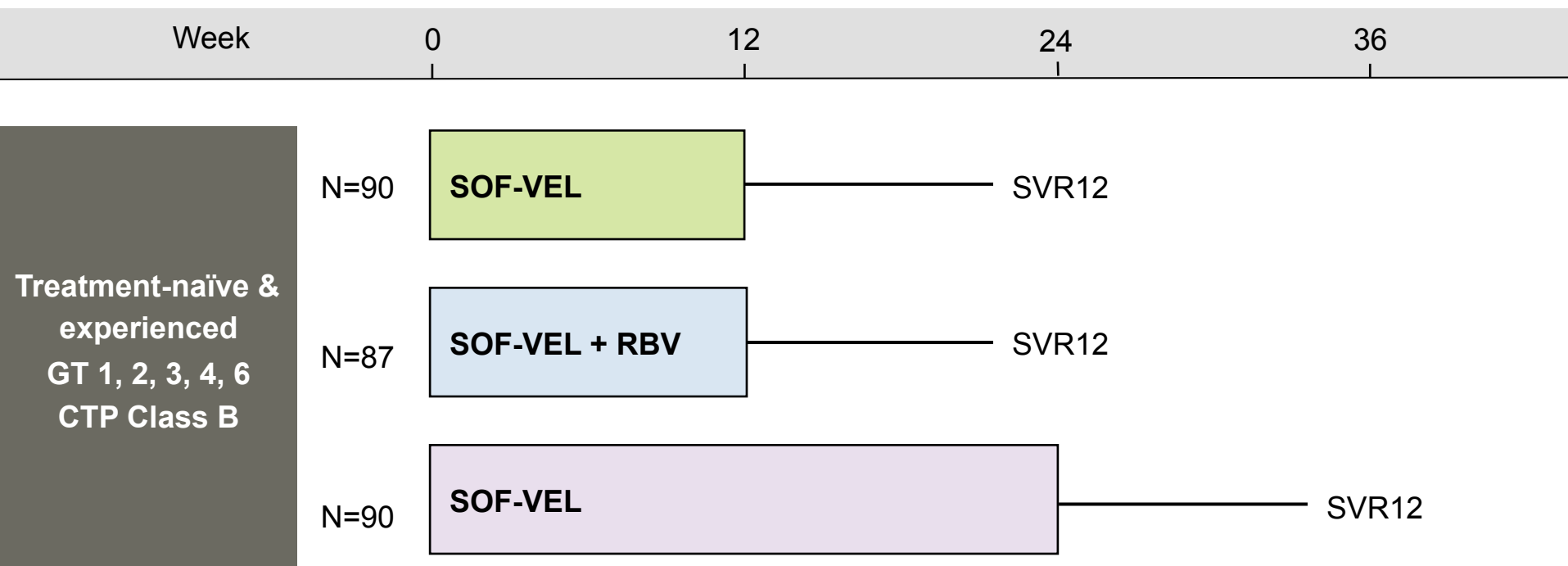
# Sofosbuvir-Velpatasvir in Decompensated HCV Cirrhosis

## ASTRAL-4: Study Features

### ASTRAL-4 Trial

- **Design:** Randomized, phase 3 trial to examine the safety and efficacy of a fixed-dose combination of sofosbuvir-velpatasvir for 12 weeks +/- ribavirin or for 24 weeks in patients with GT 1-6 chronic HCV with decompensated cirrhosis
- **Setting:** 47 sites in United States
- **Entry Criteria**
  - Chronic HCV GT 1, 2, 3, 4, 6
  - Child-Pugh-Turcotte class B
  - Prior treatment failure (except for prior NS5A or NS5B) allowed
- **Exclusion Criteria**
  - Prior or impending (within 12 weeks of study entry) liver transplantation
  - Platelet count <30,000 or CrCl <50 ml/min
- **Primary End-Point:** SVR12

# Sofosbuvir-Velpatasvir in Decompensated HCV Cirrhosis ASTRAL-4: Study Design



**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

# Sofosbuvir-Velpatasvir in Decompensated HCV Cirrhosis

## ASTRAL-4: Participants

Baseline Characteristic	SOF-VEL 12 weeks n=90	SOF-VEL + RBV 12 weeks n=87	SOF-VEL 24 weeks n=90
Mean age, years (range)	58 (42-73)	58 (40-71)	58 (46-72)
Male sex, %	63	76	70
Race, %			
White	88	91	90
Black	7	6	7
Asian	3	0	2
HCV Genotype, %			
1a	56	62	61
1b	20	16	18
2	4	5	4
3	16	15	13
4	4	2	2
6	0	0	1
HCV RNA $\geq$ 800,000 IU/mL, %	66	52	50
IL28B genotype, non-CC, %	78	75	78
Mean eGFR, ml/min (range)	89 (15-169)	90 (50-167)	90 (43-198)

Source: Curry MP, et al. N Engl J Med. 2015;373:2618-28.

# Sofosbuvir-Velpatasvir in Decompensated HCV Cirrhosis

## ASTRAL-4: Participants

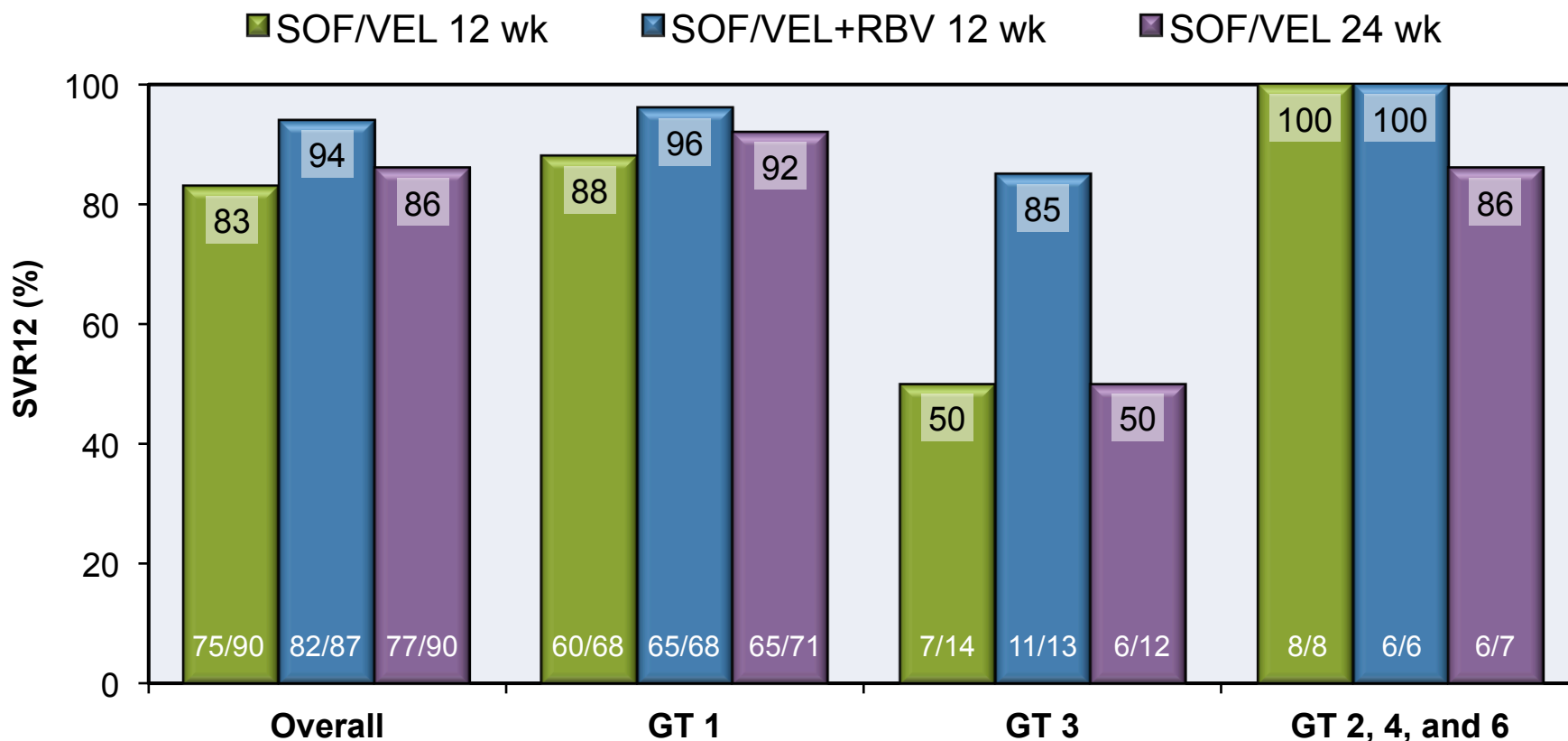
Baseline Characteristic	SOF-VEL 12 weeks n=90	SOF-VEL + RBV 12 weeks n=87	SOF-VEL 24 weeks n=90
CPT score, %			
≤6	3	7	8
7	40	26	23
8	34	47	38
9	21	15	24
10	1	5	7
MELD score, %			
<10	40	33	29
10-15	56	62	66
≥16	4	5	6
Ascites, %			
None	18	25	17
Mild or moderate	80	70	82
Severe	2	5	1
Prior HCV treatment, %			
No	36	46	53
Yes	64	54	47
Protease inhibitor regimen	16	26	17
Peginterferon + Ribavirin	83	74	83

Source: Curry MP, et al. N Engl J Med. 2015;373:2618-28.

# Sofosbuvir-Velpatasvir in Decompensated HCV Cirrhosis

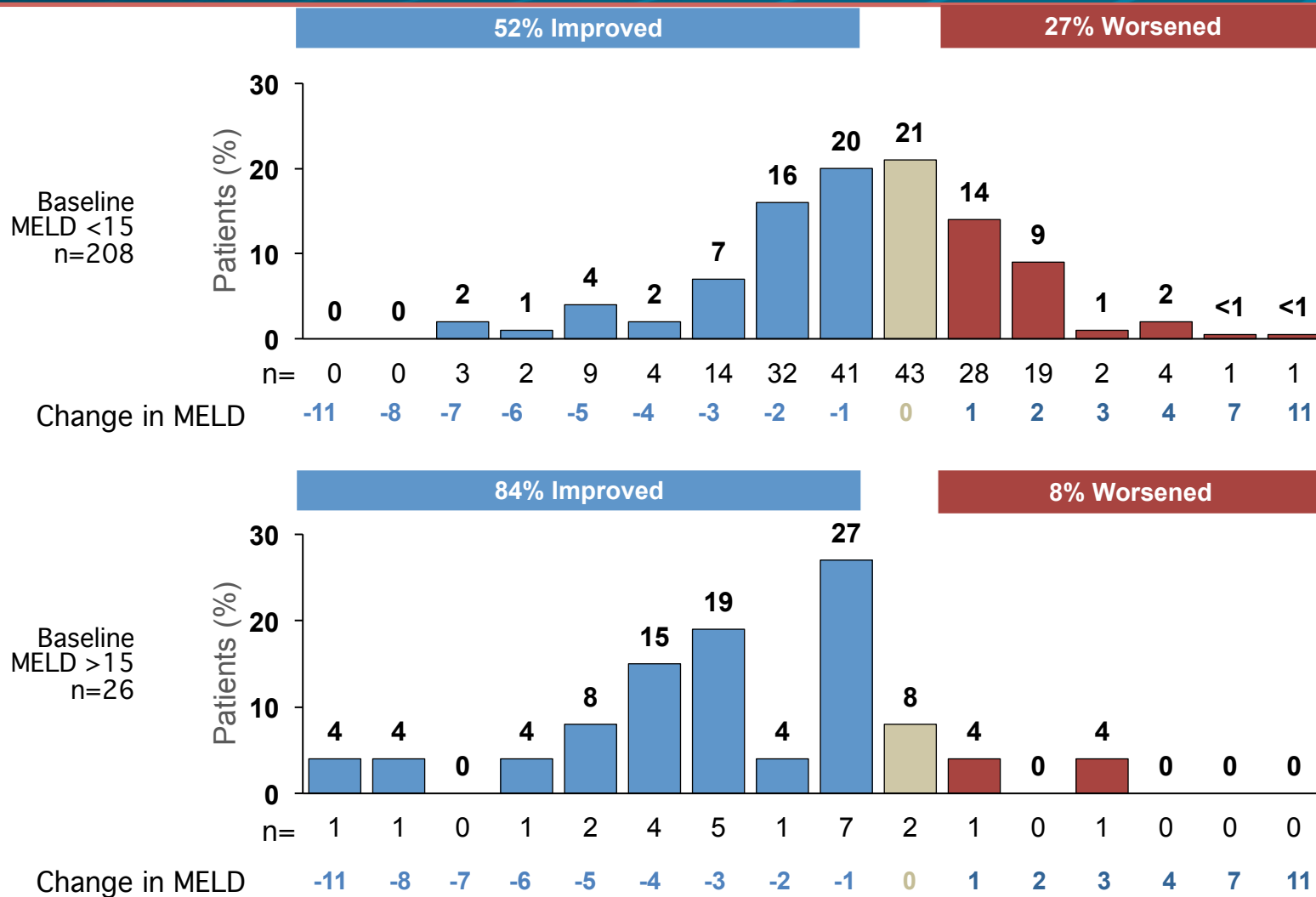
## ASTRAL-4: Results

### ASTRAL-4: SVR12 Results by Genotype



# Sofosbuvir-Velpatasvir in Decompensated HCV Cirrhosis

## ASTRAL-4: Change in MELD Scores on Treatment



# Sofosbuvir-Velpatasvir in Decompensated HCV Cirrhosis

## ASTRAL-4: Adverse Events

Adverse Event (AE), %	SOF-VEL 12 weeks (n=90)	SOF-VEL + RBV 12 weeks (n=87)	SOF-VEL 24 weeks (n=90)
Discontinuation due to AE	1	5	4
Serious AEs	19	16	18
Deaths	3	3	3
Any AE in $\geq 10\%$ of patients			
Fatigue	26	39	23
Nausea	24	25	20
Headache	26	21	19
Anemia	4	31	3
Diarrhea	7	21	8
Insomnia	10	14	10
Pruritus	11	5	4
Muscle spasm	3	11	2
Dyspnea	4	10	0
Hemoglobin <10 g/dl	8	23	9

Source: Curry MP, et al. N Engl J Med. 2015;373:2618-28.

# Sofosbuvir-Velpatasvir in Decompensated HCV Cirrhosis ASTRAL-4: Conclusions

**Conclusions:** “Treatment with sofosbuvir–velpatasvir with or without ribavirin for 12 weeks and with sofosbuvir–velpatasvir for 24 weeks resulted in high rates of sustained virologic response in patients with HCV infection and decompensated cirrhosis.”

# Sofosbuvir-Velpatasvir in HIV-HCV Coinfected Patients ASTRAL-5

Wyles D, et al. Clin Infect Dis. 2017 March 29. [Epub ahead of print]

# Sofosbuvir-Velpatasvir in HIV-HCV Coinfected Patients

## ASTRAL-5: Study Features

### ASTRAL-5 Trial

- **Design:** Single-arm, open-label, multicenter, phase 3 trial of sofosbuvir-velpatasvir in HIV-HCV coinfecting treatment-naïve and treatment-experienced patients with genotypes 1-6 HCV
- **Setting:** Multiple sites in US
- **Entry Criteria**
  - Chronic HCV GT 1-6
  - Age  $\geq 18$  years
  - HIV coinfection and on stable ART for  $\geq 8$  weeks
  - CD4 count  $\geq 100$  cells/mm<sup>3</sup> and HIV RNA  $\leq 50$  copies/mL
  - On stable ART for  $\geq 8$  weeks
  - Prior treatment failure allowed (but no prior NS5A or NS5B)
  - Patients with compensated cirrhosis allowed
- **Primary End-Point:** SVR12

# Sofosbuvir-Velpatasvir in HIV-HCV Coinfected Patients ASTRAL-5: Study Design

Week

0

12

24

HIV-HCV Coinfected  
Treatment-naïve &  
experienced  
GT 1, 2, 3, 4, or 6

n = 106

**Sofosbuvir-Velpatasvir**

SVR12

**Drug Dosing:** Sofosbuvir-velpatasvir (400/100 mg): fixed-dose combination; one pill once daily

# Sofosbuvir-Velpatasvir in HIV-HCV Coinfected Patients ASTRAL-5: Participants

Baseline Characteristic	Sofosbuvir-Velpatasvir (N=106)
Age, mean, years (range)	54 (25-72)
Male, n (%)	91 (86)
Black race, n (%)	48 (45)
HCV genotype, n (%)	
1a	66 (62)
1b	12 (11)
2	11 (10)
3	12 (11)
4	5 (5)
IL28B non-CC, n (%)	82 (77)
Mean HCV RNA, log <sub>10</sub> IU/ml (range)	6.3 (5.0-7.4)
Cirrhosis, n (%)	19 (18)
Treatment experienced, n (%)	31 (29)

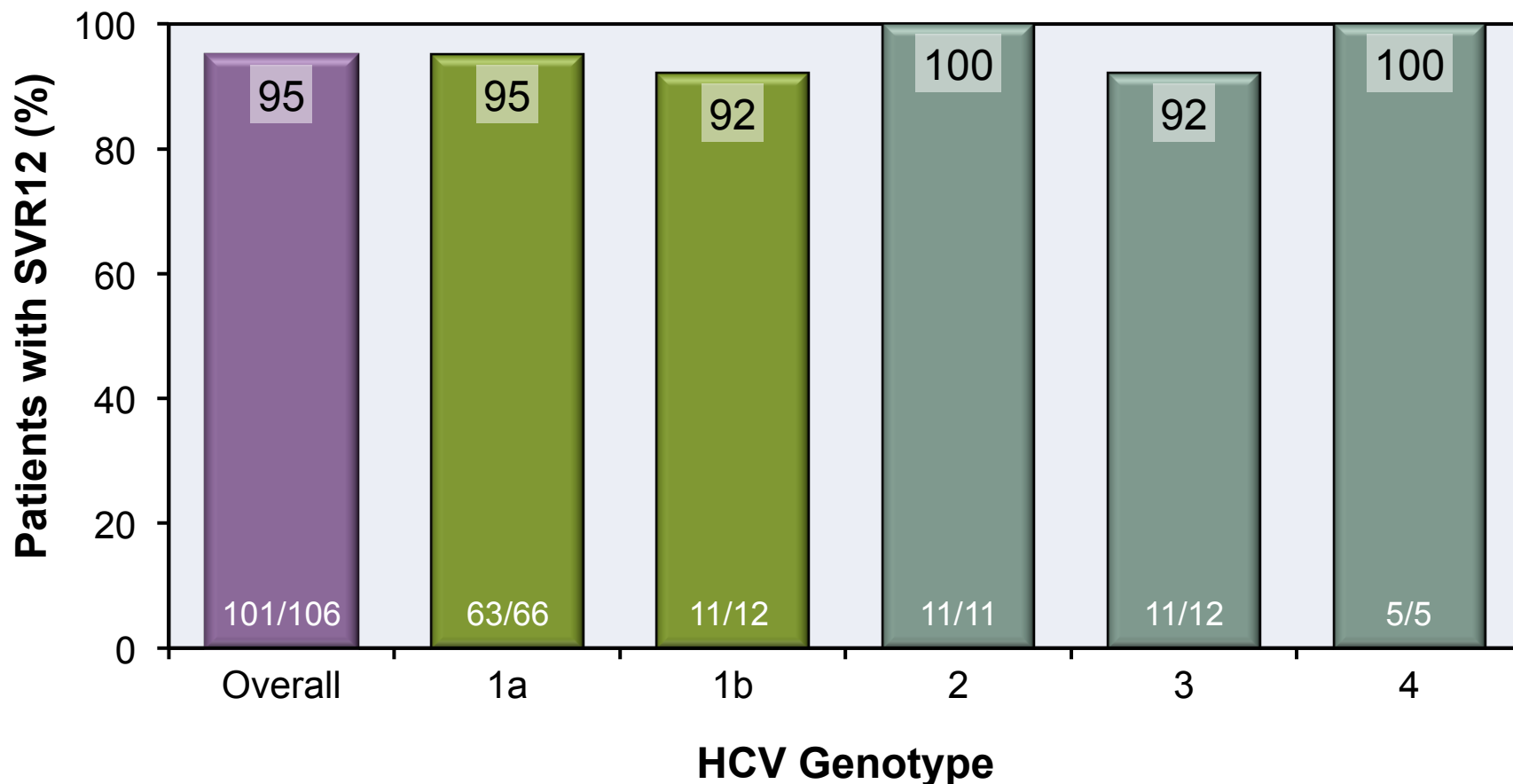
# Sofosbuvir-Velpatasvir in HIV-HCV Coinfected Patients ASTRAL-5: Participants

HIV Baseline Characteristics	Sofosbuvir-Velpatasvir (N=106)
Mean CD4 cell count, (range)	598 (183-1513)
Nucleos(t)ide pair	
TDF with boosted agent (RTV or Cobi)	56 (53)
TDF without boosted agent	35 (33)
Abacavir-lamivudine	15 (14)
Other antiretroviral agent(s)	
PI (DRV, LPV or ATV)	50 (47)
NNRTI (RPV)	13 (12)
Integrase inhibitor (RAL or EVG)	36 (34)
Other (>1 of above classes)	7 (7)

Abbreviations: TDF = Tenofovir disoproxil fumarate; RTV = ritonavir; Cobi = cobicistat;  
PI = HIV protease inhibitor; DRV = darunavir; LPV = lopinavir; ATV = atazanavir;  
PRV = rilpivirine; RAL = raltegravir; EVG = elvitegravir

# Sofosbuvir-Velpatasvir in HIV-HCV Coinfected Patients ASTRAL-5: Results

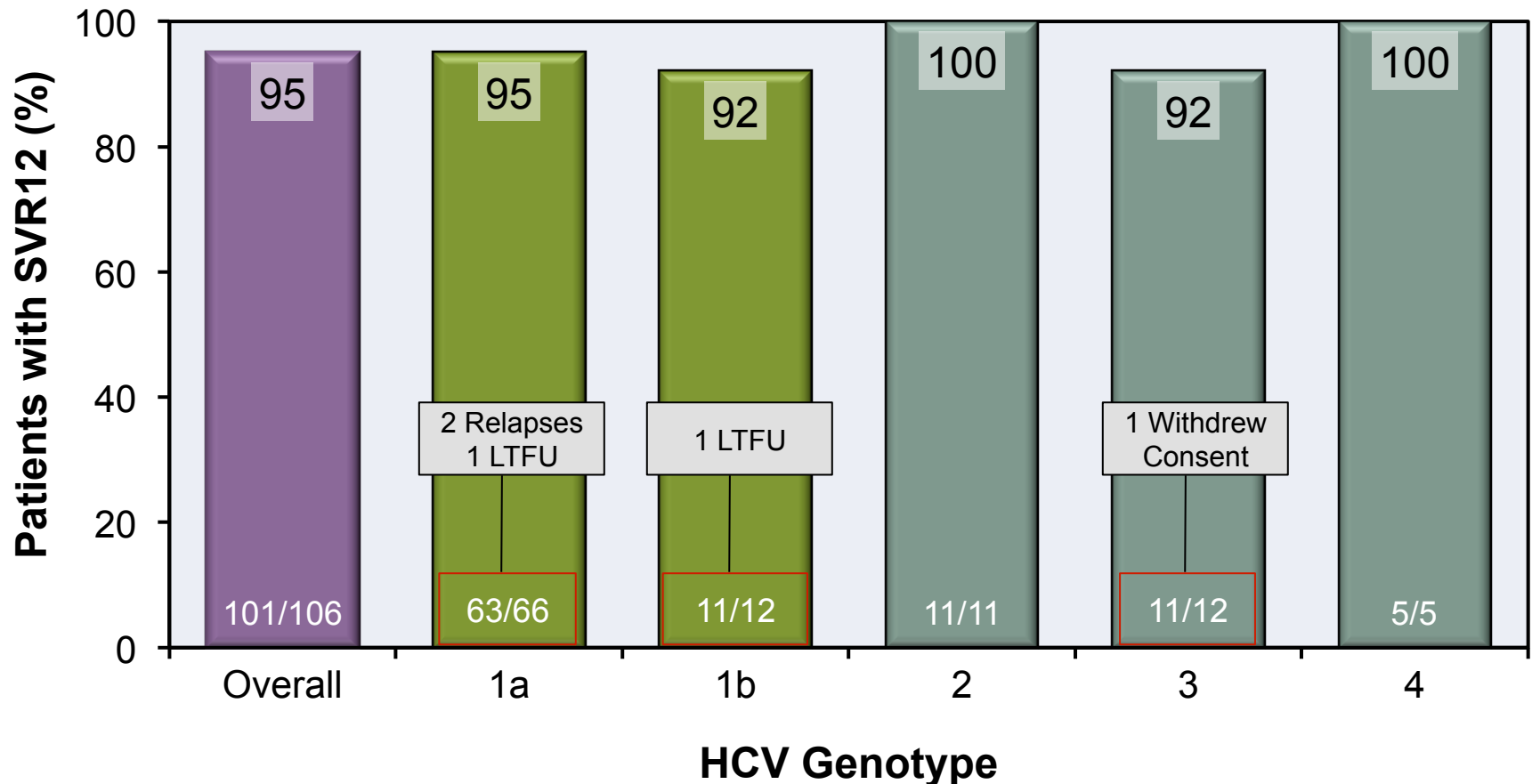
## ASTRAL-5: SVR12 Results by Genotype



# Sofosbuvir-Velpatasvir in HIV-HCV Coinfected Patients

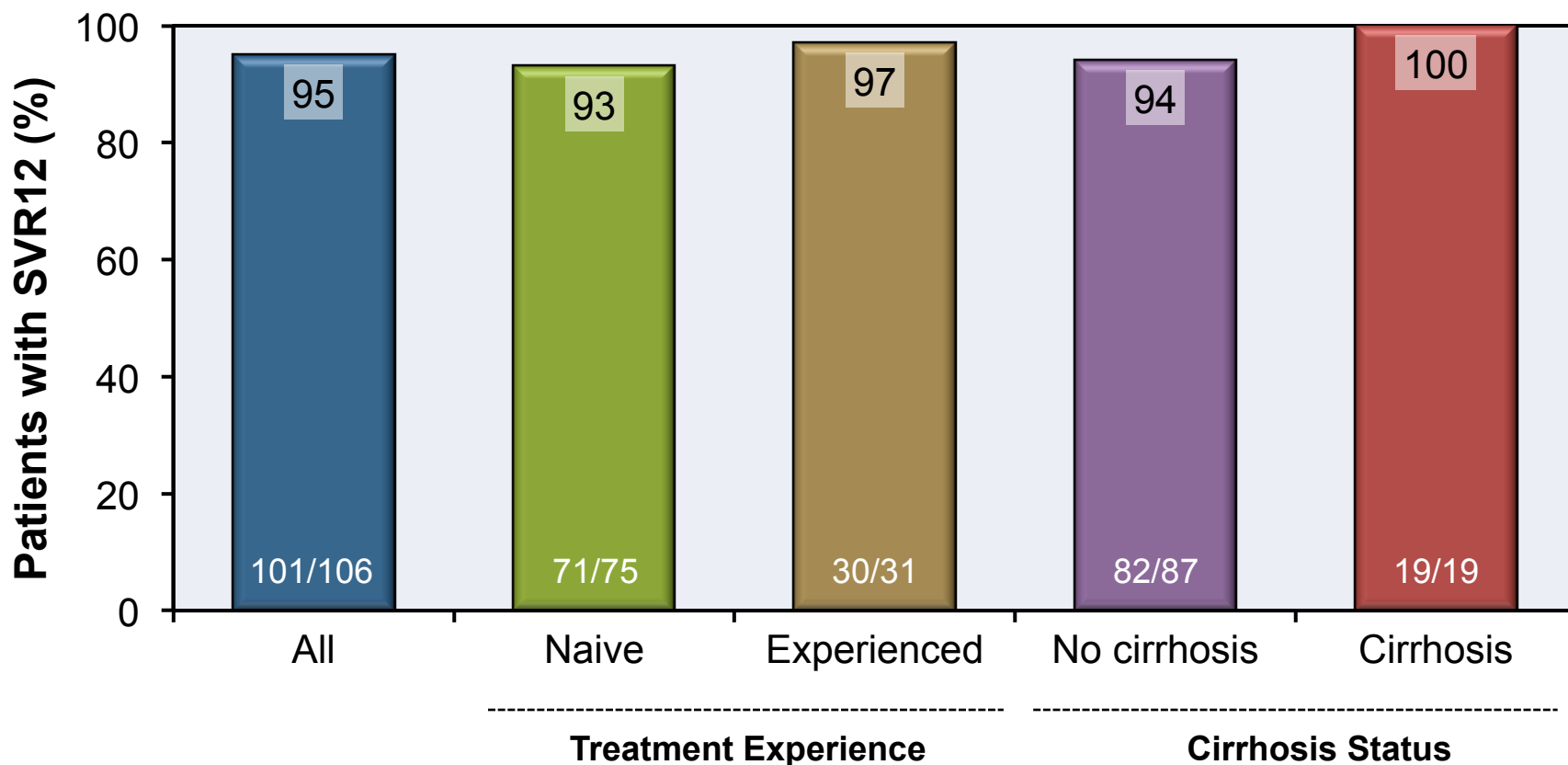
## ASTRAL-5: Results

### ASTRAL-5: SVR12 Results by Genotype



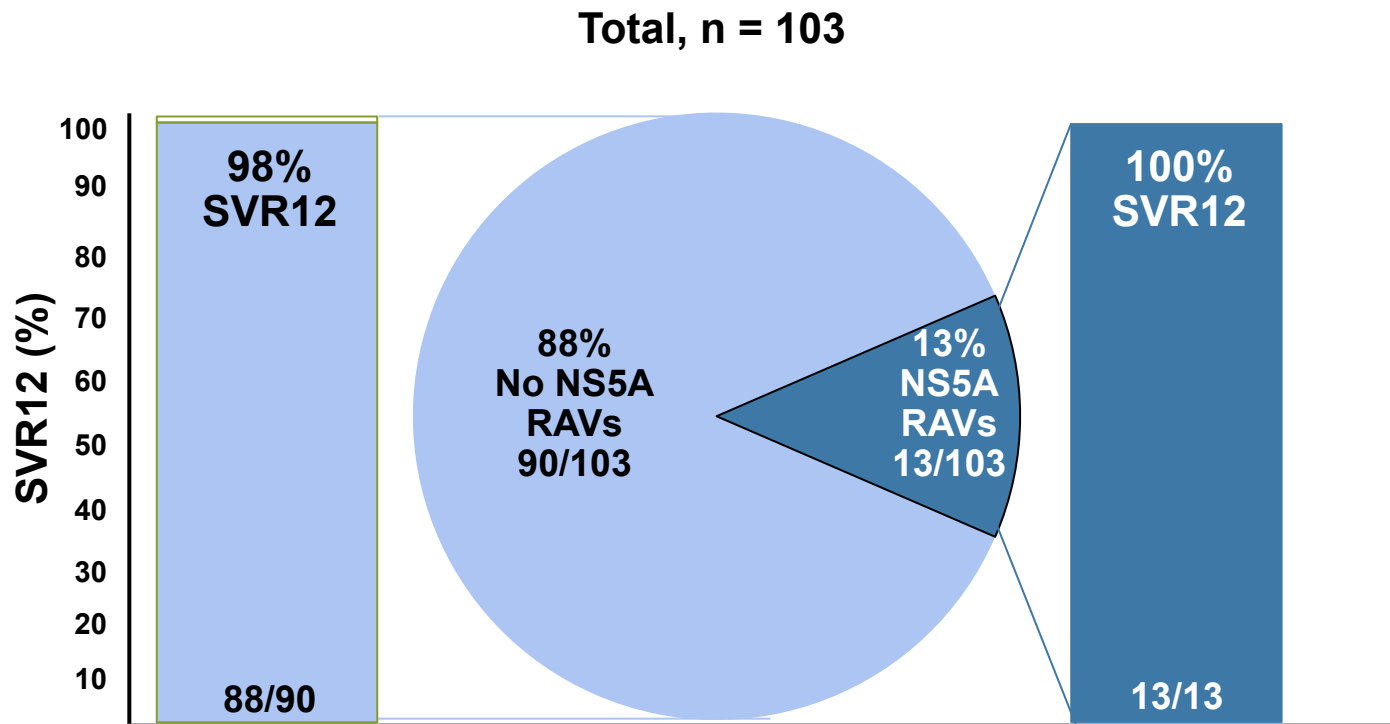
# Sofosbuvir-Velpatasvir in HIV-HCV Coinfected Patients ASTRAL-5: Results

## ASTRAL-5: SVR12 Results by Cirrhosis & Treatment Experience



# Sofosbuvir-Velpatasvir in HIV-HCV Coinfected Patients ASTRAL-5: Resistance

## Baseline NS5A Resistance-Associated Variants and SVR12



# Sofosbuvir-Velpatasvir in HIV-HCV Coinfected Patients

## ASTRAL-5: Adverse Events

Adverse Event (AE), n (%)	Sofosbuvir-Velpatasvir (N=106)
Discontinuation due to AE	2 (2)
Serious AEs	2 (2)
Deaths	0
Any AE in >5% of patients	
Fatigue	26 (25)
Headache	14 (13)
Arthralgia	9 (8)
Upper respiratory tract infection	9 (8)
Diarrhea	9 (8)
Insomnia	7 (7)
Nausea	7 (7)

The majority of AEs were mild in severity (grade 1 or 2).  
No patient with confirmed on-treatment HIV virologic breakthrough.

# Sofosbuvir-Velpatasvir in HIV-HCV Coinfected Patients ASTRAL-5: Conclusions

**Conclusions:** “Sofosbuvir-velpatasvir for 12 weeks was safe and provided high rates of SVR12 in patients coinfecting with HCV and HIV-1.”