HEPATITIS WEB STUDY HEPATITIS C ONLINE

Ledipasvir-Sofosbuvir (*Harvoni*)

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Hepatitis web study

Robert Gish, MD: Disclosures

- **Research Support**: Bristol-Myers Squibb, Gilead Sciences, Merck & Co.
- **Consulting Board**: Bristol-Myers Squibb, Gilead, Merck & Co., Janssen, Abbvie, Idenix
- **Honoraria for Promotional Talks**: Bristol-Myers Squibb, AbbVie, Gilead Sciences, Merck & Co., Janssen

LEDIPASVIR-SOFOSBUVIR

Background and Dosing

Ledipasvir-Sofosbuvir (*Harvoni*)

- **Approval Status**: FDA approved October 10, 2014

- **Indications and Usage**
  - Indicated for the treatment of chronic HCV genotype 1 in adults

- **Class & Mechanism**
  - Ledipasvir: NS5A inhibitor
  - Sofosbuvir: Nucleotide analog NS5B polymerase inhibitor

- **Dosing:** Ledipasvir-Sofosbuvir (fixed dose 90 mg/400 mg)
  One tablet orally once daily with or without food

- **Adverse Effects (AE)**: Fatigue, headache

- **Drug Drug interactions:** Minor

Source: *Harvoni* Prescribing Information. Gilead Sciences

Ledipasvir-Sofosbuvir (*Harvoni*)
Indications and Usage

Genotype 1 Patient Populations	Treatment Duration*
Treatment naïve with or without cirrhosis	12 weeks
Treatment experienced** without cirrhosis	12 weeks
Treatment experienced** with cirrhosis	24 weeks

*Consider treatment duration of 8 weeks in treatment-naïve patients without cirrhosis who have a pretreatment HCV RNA less than 6 million IU/mL

**Treatment-experienced patients who have failed treatment with either (a) peginterferon alfa plus ribavirin or (b) HCV protease inhibitor plus peginterferon alfa plus ribavirin

Source: *Harvoni* Prescribing Information. Gilead Sciences

Ledipasvir-Sofosbuvir (*Harvoni*)
Estimated Cost of Therapy

Estimated Cost of Ledipasvir-Sofosbuvir Based on Treatment Duration	
Duration of Treatment	**Estimated Cost***
8 Weeks	$63,000
12 Weeks	$94,500
24 Weeks	$189,000

*Estimated cost based on Wholesaler Acquisition Cost in United States of $1125 per pill

Source: *Harvoni* Prescribing Information. Gilead Sciences

Ledipasvir-Sofosbuvir (*Harvoni*)
Drug-Drug Interactions

- **Not recommended for coadministration with:**
  - P-gp inducers (eg. Rifampin-like drugs, St. John's Wort)

- **Consult Prescribing Information Regarding Interactions with the following classes of medications**:
  - Acid reducing agents (Antacids, PPIs, H2 Blockers)
  - Antiarrhythmics
  - Anticonvulsants
  - Antimycobacterials
  - HIV antiretrovirals

Source: *Harvoni* Prescribing Information. Gilead Sciences

Ledipasvir-Sofosbuvir (*Harvoni*)
Adverse Effects

Adverse Effects with Ledipasvir-Sofosbuvir Reported in ≥5% of Subjects			
	Ledipasvir-Sofosbuvir		
	8 Weeks	12 Weeks	24 Weeks
	N=215	N=539	N=326
Fatigue	16%	13%	18%
Headache	11%	14%	17%
Nausea	6%	7%	9%
Diarrhea	4%	3%	7%
Insomnia	3%	5%	6%

Source: *Harvoni* Prescribing Information. Gilead Sciences

STUDIES

Ledipasvir-Sofosbuvir

Ledipasvir-Sofosbuvir (*Harvoni*)
Summary of Key **Phase 3** Studies

- **ION-3**
  - Treatment-naïve non-cirrhotic GT 1
  - LDV-SOF +/- Ribavirin x 8 weeks vs LDV/SOF x 12 weeks
- **ION-1**
  - Treatment-naïve GT 1
  - LDV-SOF with or without Ribavirin for 12 or 24 weeks
- **ION-2**
  - Treatment-experienced GT 1
  - LDV-SOF with or without Ribavirin for 12 or 24 weeks

Treatment Naïve

Ledipasvir-Sofosbuvir +/- Ribavirin for 8 or 12 weeks in HCV GT1

ION-3

Source: Kowdley K, et al. N Engl J Med. 2014;370:1879-88.

Ledipasvir-Sofosbuvir for 8 or 12 Weeks in Treatment-Naïve HCV GT 1

ION-3 Study: Features

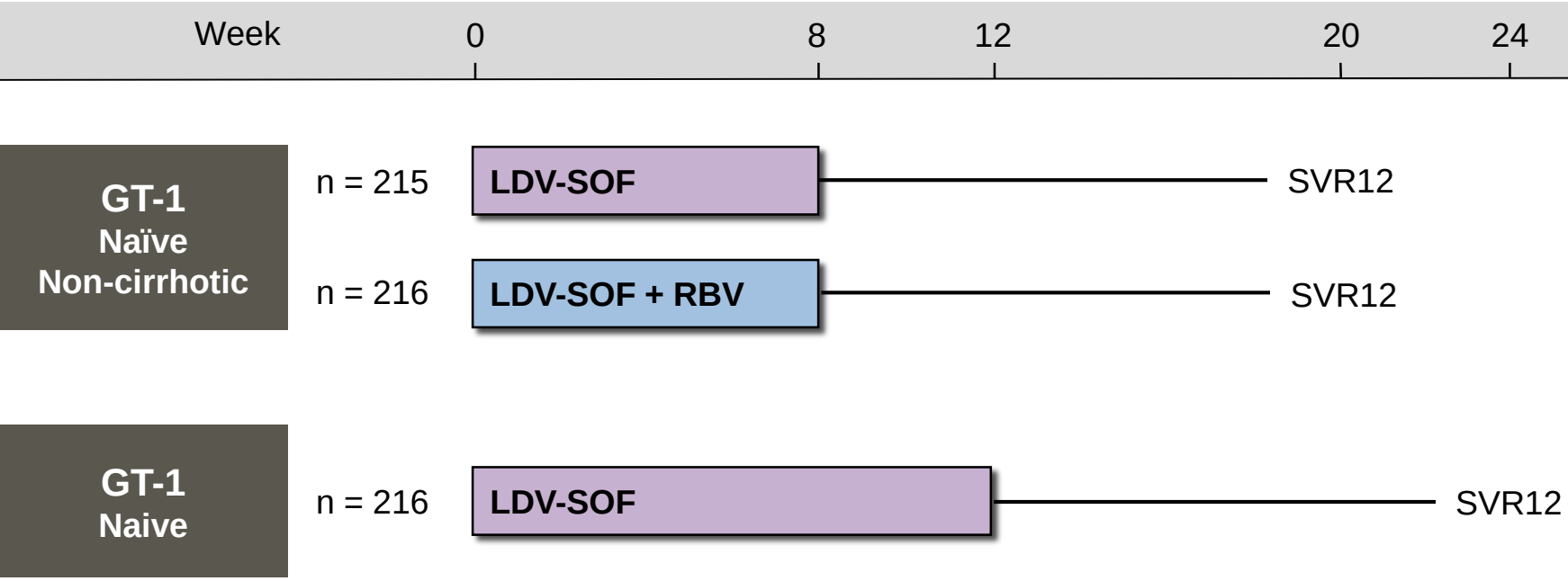
ION-3 Trial

- **Design**: Open-label, randomized, phase 3, using fixed-dose combination of ledipasvir-sofosbuvir with or without ribavirin for 8 or 12 weeks in treatment-naïve, non-cirrhotic patients with GT1 HCV
- **Setting**: 58 sites in United States
- **Entry Criteria**
  - Chronic HCV Genotype 1 (n=647)
  - 18 years or older
  - No prior HCV treatment
  - Patients with cirrhosis were excluded
  - HCV RNA ≥ 10,000 IU/ml
  - No limits on BMI
- **Primary End-Point**: SVR12

Source: Kowdley, K, et al. N Engl J Med. 2014;370:1879-88.

Ledipasvir-Sofosbuvir for 8 or 12 Weeks in Treatment-Naïve HCV GT 1

ION-3 Study: Study Design



Abbreviations: LDV= ledipasvir; SOF = sofosbuvir; RBV = ribavirin

Drug Dosing

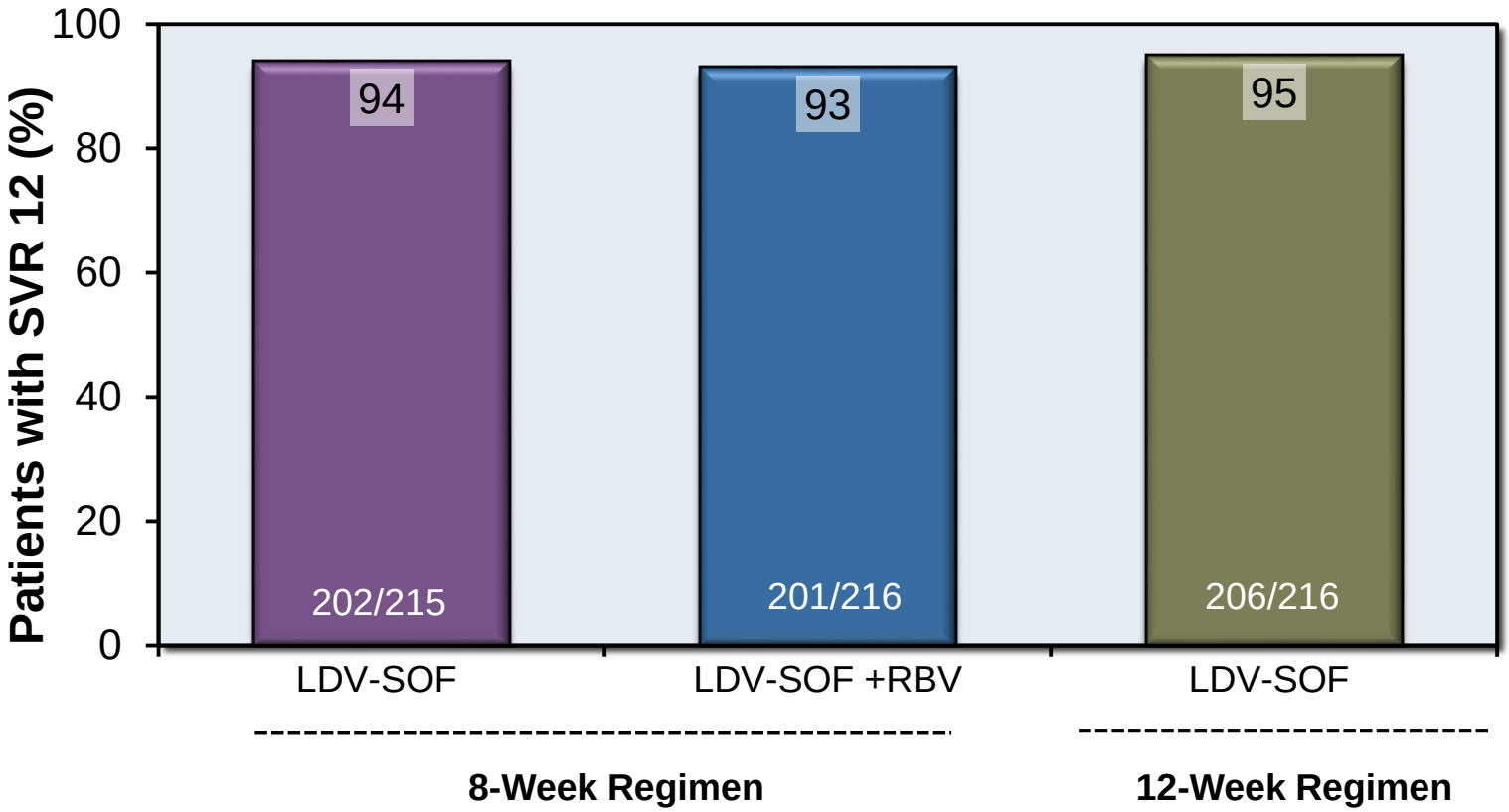
Ledipasvir-sofosbuvir (90/400 mg): fixed dose combination; one pill once daily

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

Source: Kowdley, K, et al. N Engl J Med. 2014;370:1879-88.

Ledipasvir-Sofosbuvir for 8 or 12 Weeks in Treatment-Naïve HCV GT 1
ION-3 Study: Results

ION-3: SVR 12* by Treatment Duration and Regimen



Abbreviations: LDV-SOF= ledipasvir-sofosbuvir; RBV = ribavirin
*Primary end-point by intention-to-treat analysis

Source: Kowdley, K, et al. N Engl J Med. 2014;370:1879-88.

Ledipasvir-Sofosbuvir for 8 or 12 Weeks in Treatment-Naïve HCV GT 1

ION-3 Study: Results

Response to Ledipasvir-Sofosbuvir Based on 8 or 12 Weeks of Therapy		
	8 Weeks	12 Weeks
	N=215	N=216
Number of Responders at End of Treatment	100% (215/215)	100% (216/216)
SVR	94% (202/215)	96% (202/215)
Relapse	5% (11/215)	1% (3/216)
Relapse According to Baseline HCV RNA		
HCV RNA ≤6 million IU/mL	2% (2/123)	2% (2/131)
HCV RNA ≥6 million IU/mL	10% (9/92)	1% (1/85)

Source: *Harvoni* Prescribing Information. Gilead Sciences

Ledipasvir-Sofosbuvir for 8 or 12 Weeks in Treatment-Naïve HCV GT 1
ION-3 Study: Resistance Data

- **NS5B S282T variant (reduces susceptibility to sofosbuvir)**
  - Not observed in any patients at baseline or after treatment by deep sequencing
- **NS5A resistant variants**
  - Baseline resistance in 116 (18%) of 647 patients
  - SVR12 in 104 (90%) of 116 patients with NS5A resistance at baseline
  - Of the 23 patients who had viral relapse, 15 (65%) had NS5A-resistant variants at time of relapse
- **Resistance testing not advised since 12 weeks of therapy would be used in the at risk group with 100% SVR**

Source: Kowdley, K, et al. N Engl J Med. 2014;370:1879-88.

Treatment Naïve

Ledipasvir-Sofosbuvir +/- Ribavirin in HCV Genotype 1

ION-1

Source: Afdhal N, et al. N Engl J Med. 2014;370:1889-98.

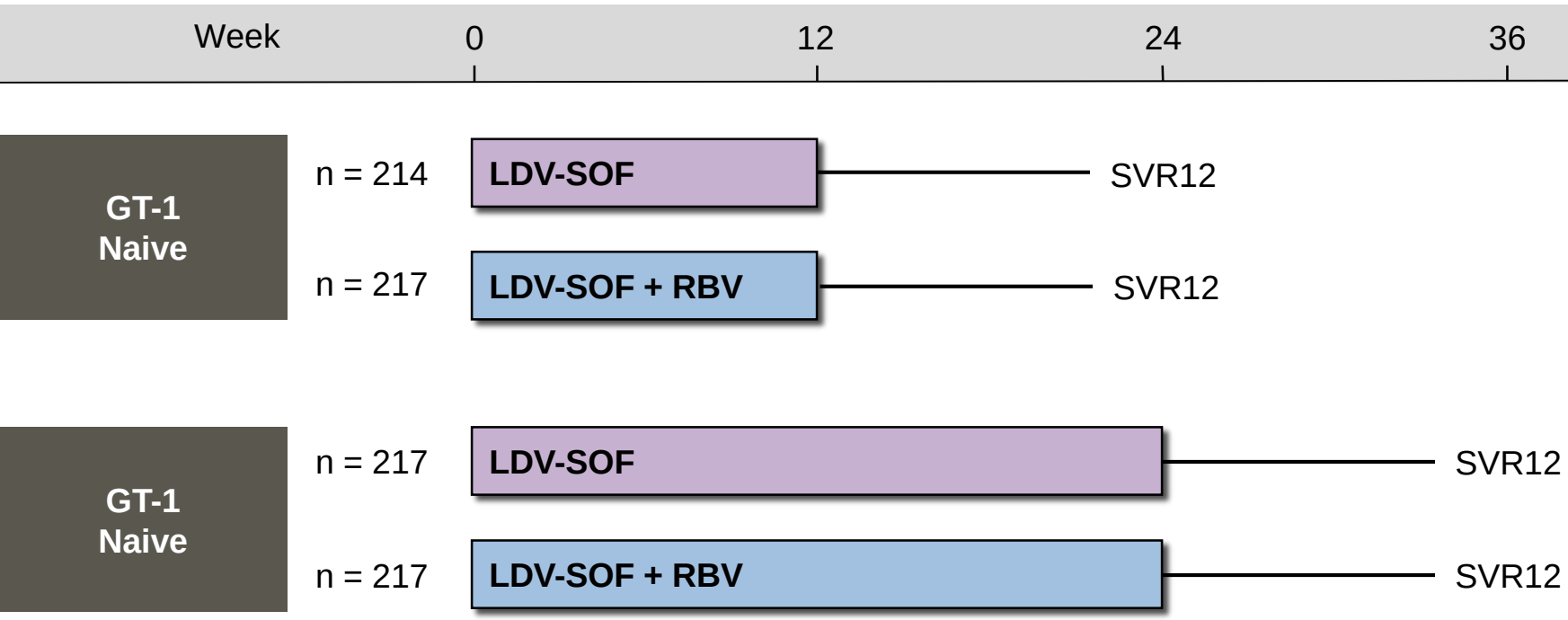
Ledipasvir-Sofosbuvir +/- Ribavirin in Treatment-Naïve HCV GT 1
ION-1 Study: Features

ION-1 Trial

- **Design**: Open-label, randomized, phase 3 trial using fixed-dose combination of ledipasvir-sofosbuvir +/- ribavirin for 12 or 24 weeks in treatment-naïve patients with GT1 HCV
- **Setting**: 99 sites in United States and Europe
- **Entry Criteria**
  - Chronic HCV Genotype 1 (n=865)
  - 18 years or older
  - No prior HCV treatment
  - Patients with cirrhosis accepted (up to 20% of patients)
- **Primary End-Point**: SVR12

Source: Afdhal N, et al. N Engl J Med. 2014;370:1889-98.

Ledipasvir-Sofosbuvir +/- Ribavirin in Treatment-Naïve HCV GT 1
ION-1 Study: Study Design



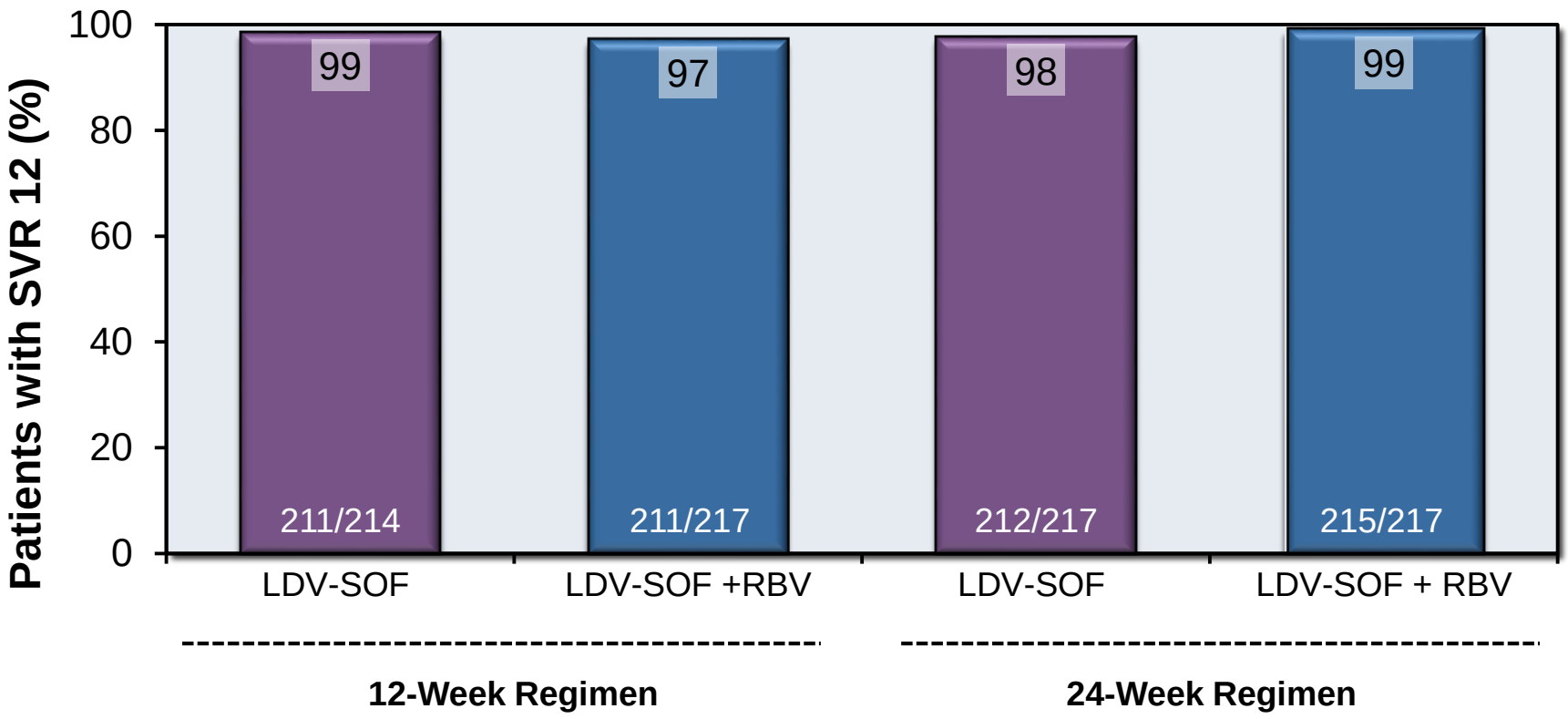
Abbreviations: LDV-SOF= ledipasvir-sofosbuvir; RBV = ribavirin

Drug Dosing
Ledipasvir-sofosbuvir (90/400 mg): fixed dose combination; one pill once daily
Ribavirin (weight-based and divided bid): 1000 mg/day if < 75 kg or 1200 mg/day if ≥ 75 kg

Source: Afdhal N, et al. N Engl J Med. 2014;370:1889-98.

Ledipasvir-Sofosbuvir +/- Ribavirin in Treatment-Naïve HCV GT 1
ION-1 Study: Results

ION-1: SVR 12* by Treatment Duration and Regimen

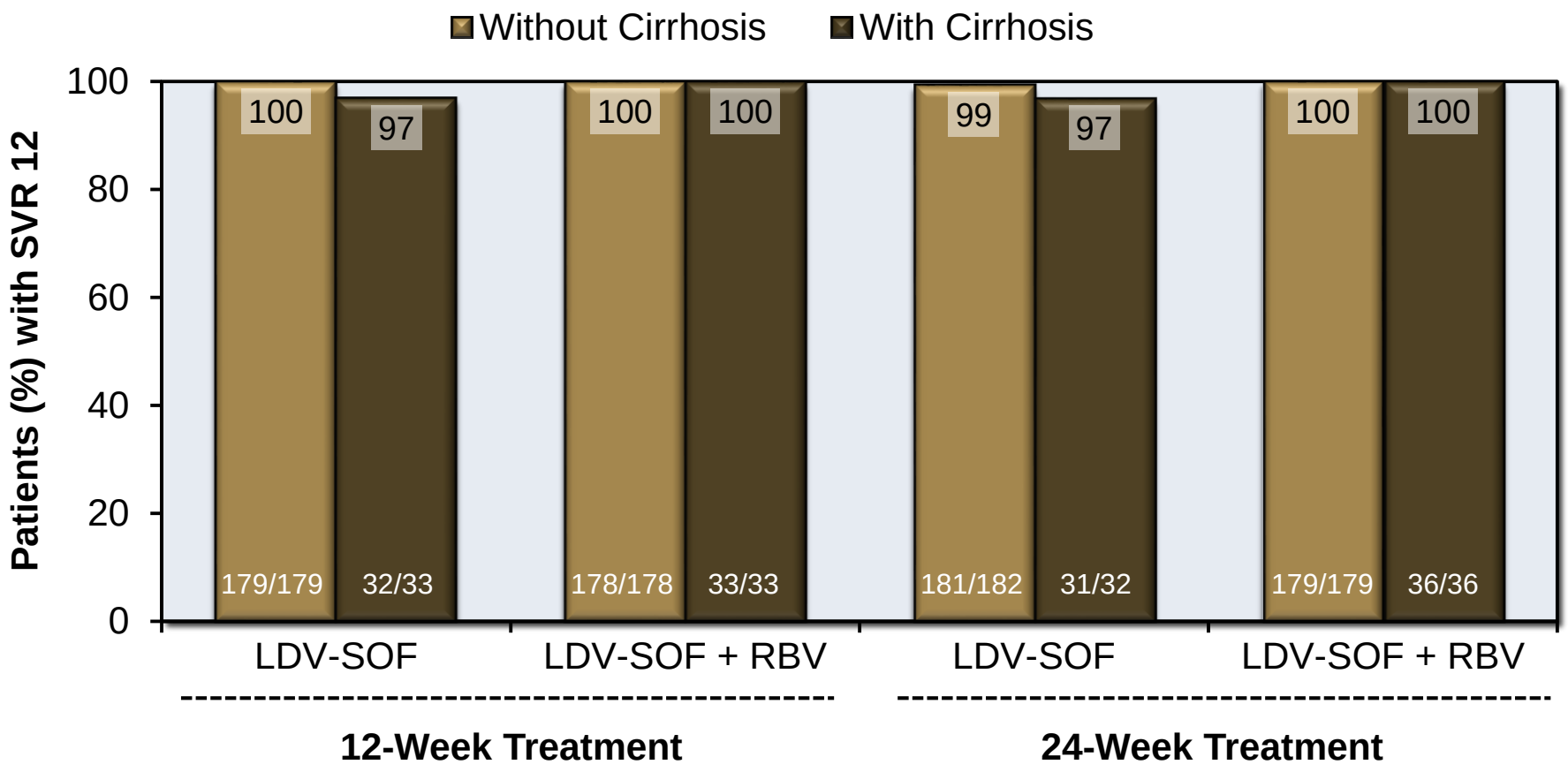


Abbreviations: LDV-SOF= ledipasvir-sofosbuvir; RBV = ribavirin
*Primary end-point by intention-to-treat analysis

Source: Afdhal N, et al. N Engl J Med. 2014;370:1889-98.

Ledipasvir-Sofosbuvir +/- Ribavirin in Treatment-Naïve HCV GT 1
ION-1 Study: Results

ION-1: SVR12 by Treatment Regimen and Liver Disease



Note: subgroup results do not include patients who withdrew consent or were lost to follow-up

Source: Afdhal N, et al. N Engl J Med. 2014;370:1889-98.

Treatment Experienced

Ledipasvir-Sofosbuvir +/- Ribavirin in HCV Genotype 1

ION-2

Source: Afdhal N, et al. N Engl J Med. 2014;370:1483-93.

Ledipasvir-Sofosbuvir +/- Ribavirin in Treatment-Experienced HCV GT 1

ION-2 Study: Features

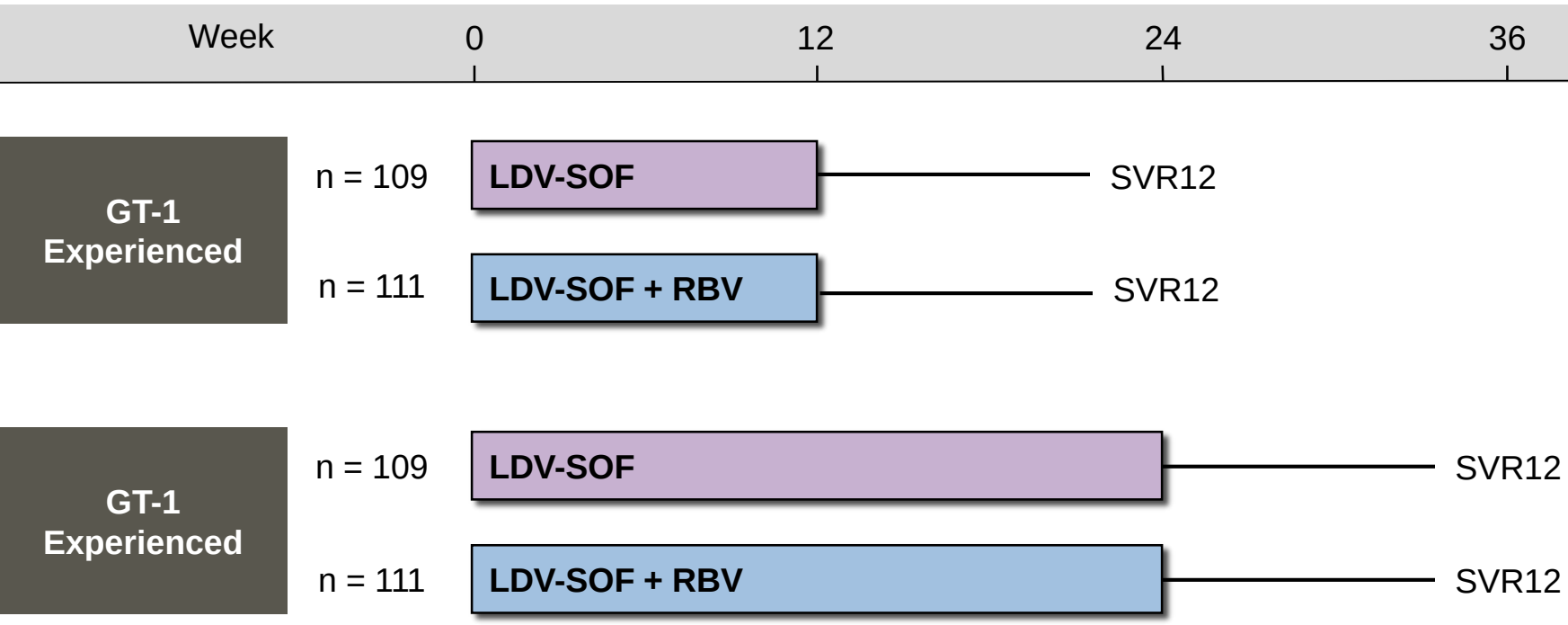
ION-2 Trial

- **Design**: Open-label, randomized, phase 3, using fixed-dose combination of ledipasvir-sofosbuvir with or without ribavirin for 12 or 24 weeks in treatment-experienced patients with GT1 HCV
- **Setting**: 64 sites in United States
- **Entry Criteria**
  - Chronic HCV Genotype 1 (n=440)
  - 18 years or older
  - Treatment experienced
  - Did not achieved SVR with prior dual therapy (peginterferon + ribavirin), or triple therapy (NS3/4A protease inhibitor plus peginterferon + ribavirin)
  - Patients with cirrhosis accepted (up to 20% of patients)
- **Primary End-Point**: SVR12

Source: Afdhal N, et al. N Engl J Med. 2014;370:1483-93.

Ledipasvir-Sofosbuvir +/- Ribavirin in Treatment-Experienced HCV GT 1

ION-2 Study: Study Design



Abbreviations: LDV= ledipasvir; SOF = sofosbuvir; RBV = ribavirin

Drug Dosing

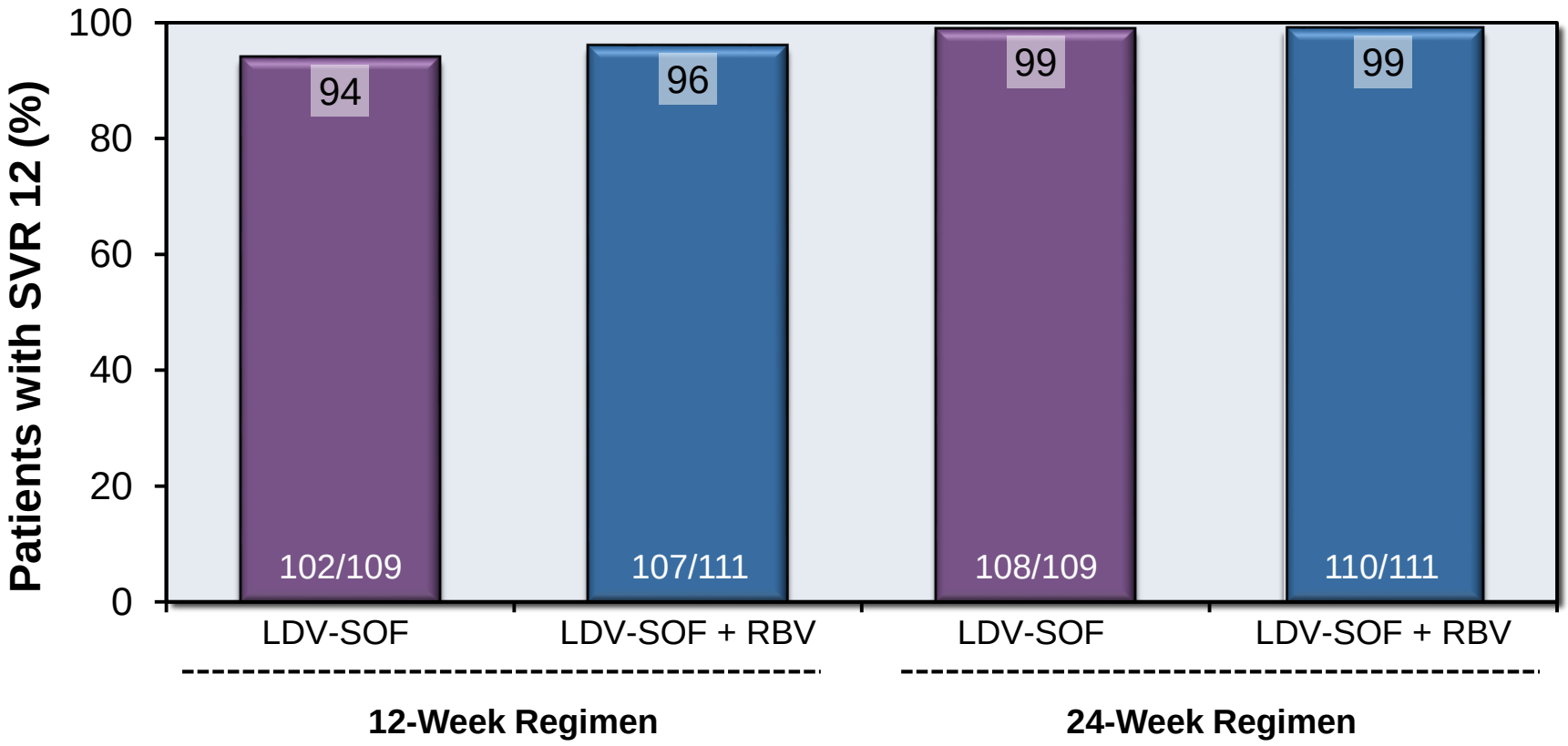
Ledipasvir-sofosbuvir (90/400 mg): fixed dose combination; one pill once daily

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

Source: Afdhal N, et al. N Engl J Med. 2014;370:1483-93.

Ledipasvir-Sofosbuvir +/- Ribavirin in Treatment-experienced HCV GT 1
ION-2 Study: Results

ION-2: SVR 12* by Treatment Duration and Regimen

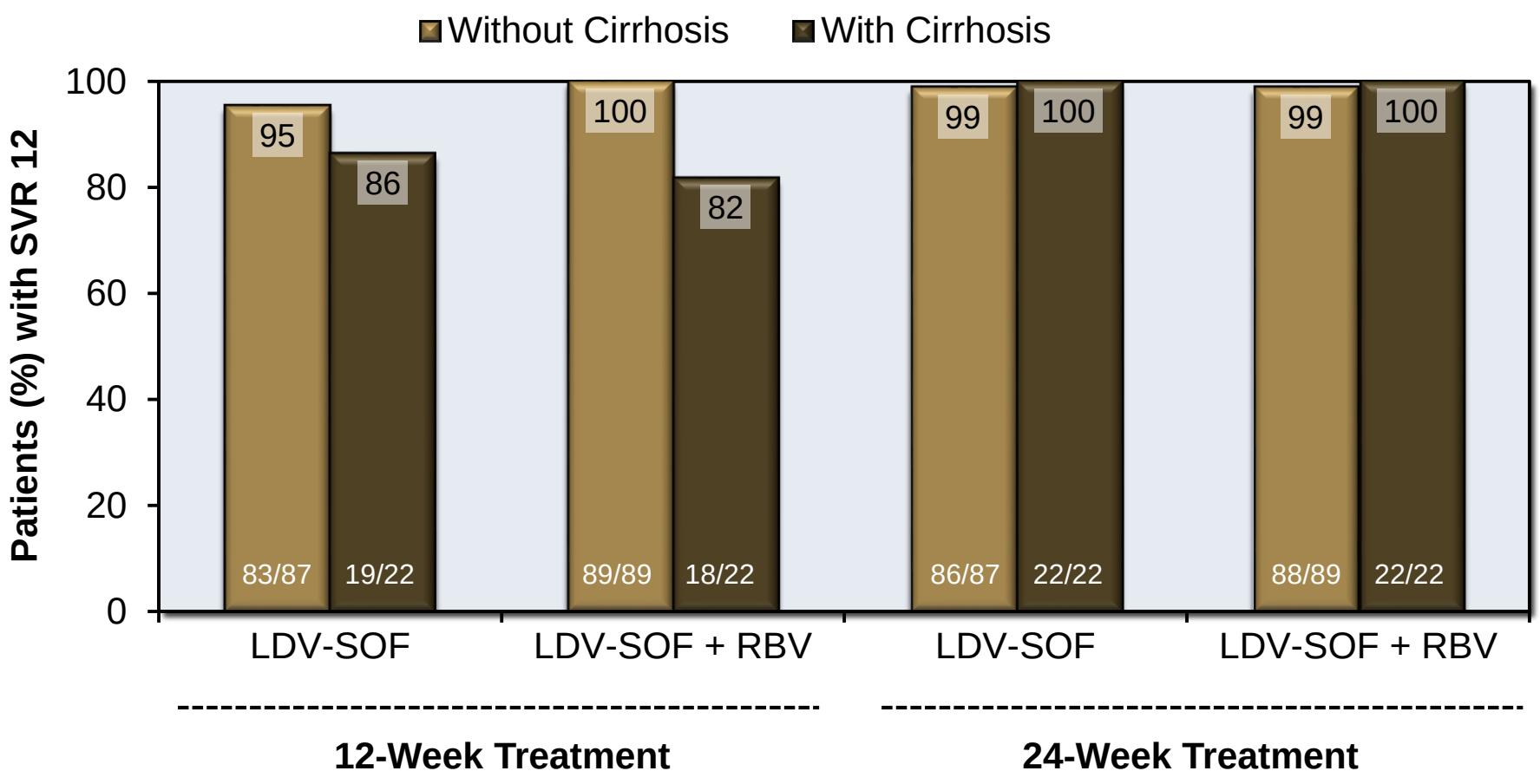


Abbreviations: LDV-SOF= ledipasvir-sofosbuvir; RBV = ribavirin
*Primary end-point by intention-to-treat analysis

Source: Afdhal N, et al. N Engl J Med. 2014;370:1483-93.

Ledipasvir-Sofosbuvir +/- Ribavirin in Treatment-experienced HCV GT 1
ION-2 Study: Results

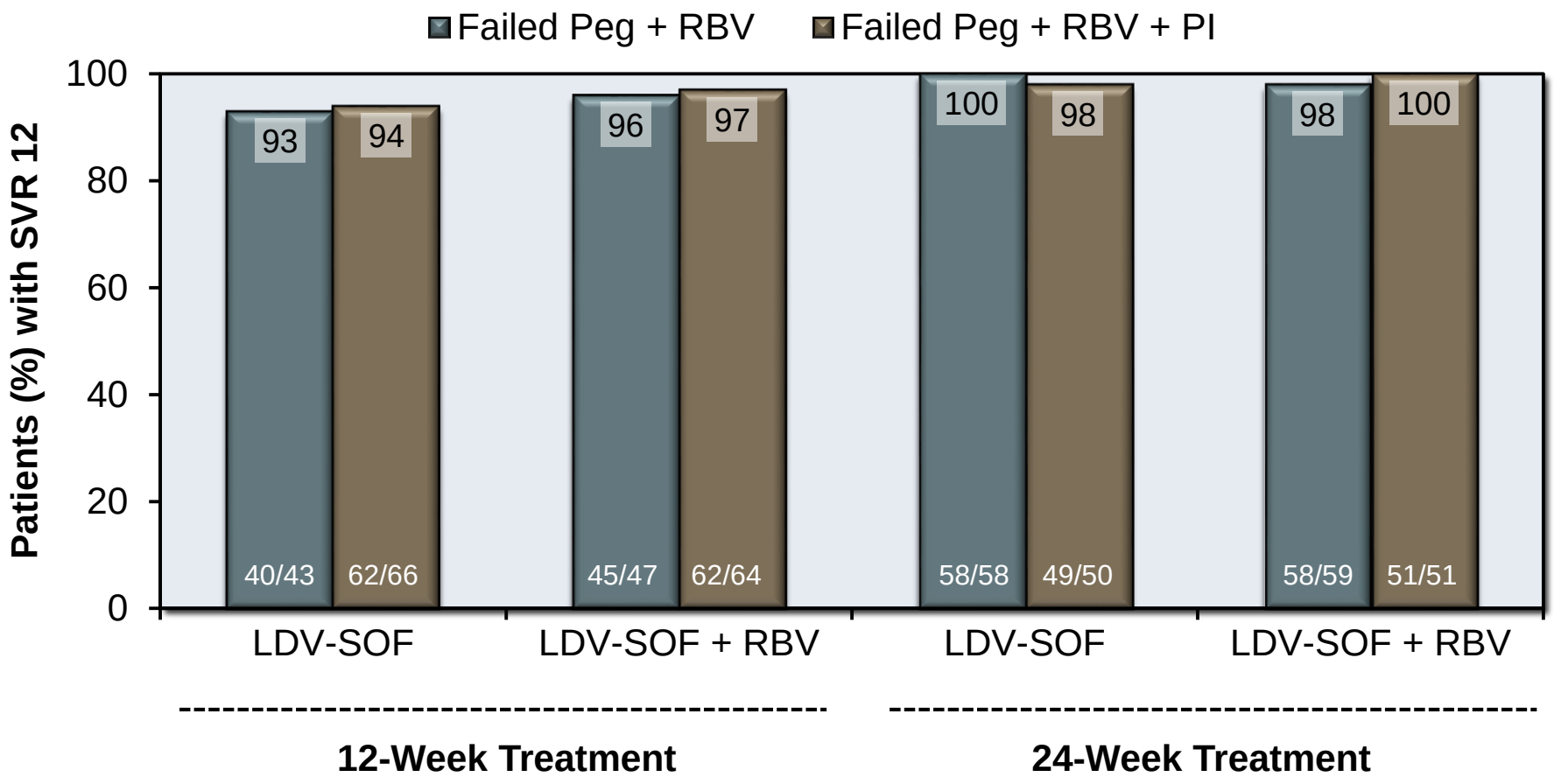
ION-2: SVR12 by Treatment Regimen and Liver Disease



Source: Afdhal N, et al. N Engl J Med. 2014;370:1483-93.

Ledipasvir-Sofosbuvir +/- Ribavirin in Treatment-experienced HCV GT 1
ION-2 Study: Results

ION-2: SVR12 by Prior Treatment Regimen



Source: Afdhal N, et al. N Engl J Med. 2014;370:1483-93.

Ledipasvir-Sofosbuvir Fixed-Dose Combination +/- RBV
Summary: ION-1, ION-2, and ION-3

Study	Population	Treatment	Duration	SVR 12 Rates
ION-1* (n= 865)	GT-1 Treatment-naïve (16% with cirrhosis)	LDV/SOF	12 weeks	99% (211/214)
		LDV/SOF + RBV	12 weeks	97% (211/217)
		LDV/SOF	24 weeks	98% (212/217)
		LDV/SOF + RBV	24 weeks	99% (215/217)
ION-2+ (n= 440)	GT-1 Treatment-experienced (20% with cirrhosis)	LDV/SOF	12 weeks	94% (102/109)
		LDV/SOF + RBV	12 weeks	96% (107/111)
		LDV/SOF	24 weeks	99% (108/109)
		LDV/SOF + RBV	24 weeks	99% (110/111)
ION-3^ (n= 647)	GT-1 Treatment-naïve (0% with cirrhosis)	LDV/SOF	8 weeks	94% (202/215)
		LDV/SOF + RBV	8 weeks	93% (201/216)
		LDV/SOF	12 weeks	95% (206/216)

***Afdhal N, et al. N Engl J Med. 2014;370:1889-98.**
+Afdhal N, et al. N Engl J Med. 2014;370:1483-93.
^Kowdley, K, et al. N Engl J Med. 2014;370:1879-88.

Treatment Naïve (unfavorable baseline treatment characteristics)

Ledipasvir-Sofosbuvir +/- 3rd DAA in HCV Genotype 1

SYNERGY

Kohli A, et al. 21st CROI. 2014:Abstract 27LB.

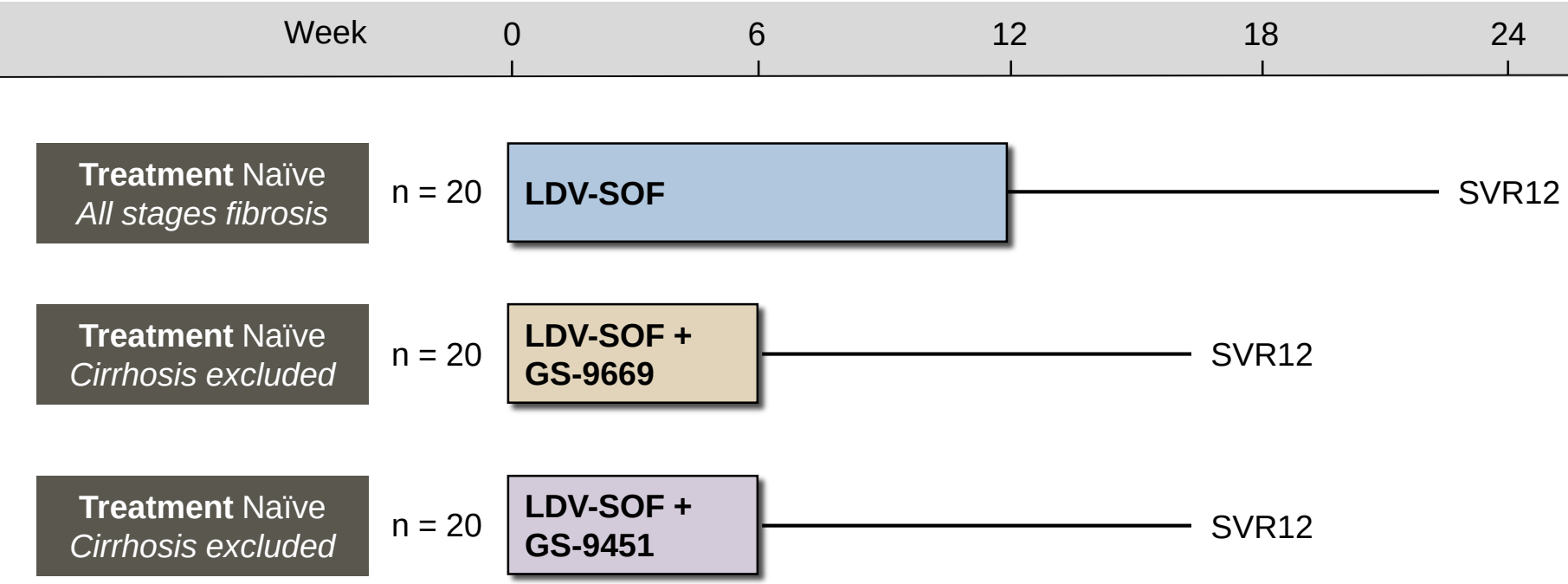
Ledipasvir-Sofosbuvir +/- [GS-9669 or GS-9451] in Naïve GT1
SYNERGY Trial: Features

SYNERGY Trial

- **Design**: Open-label, phase 2, using fixed dose ledipasvir-sofosbuvir alone or in combination with either GS-9669 (non-nucleoside NS5B inhibitor) or GS-9451 (NS3/4A protease inhibitor) in treatment-naïve GT 1
- **Setting**: single site, United States
- **Entry Criteria**
  - Chronic HCV Genotype 1
  - Treatment naive
  - HCV RNA > 50,000 IU/mL
- **Patient Characteristics**
  - N = 60 adult patients
  - Demographics: 72% male; 88% black
  - IL28B Genotype: 80% with non-CC
  - Liver Fibrosis: 70% Knodell HAI Fibrosis score 0-2
- **Primary End-Point**: SVR12

Source: Kohli A, et al. 21st CROI. 2014:Abstract 27LB.

Ledipasvir-Sofosbuvir +/- [GS-9669 or GS-9451] in Naïve GT1 SYNERGY Trial: Features



Abbreviations: LDV-SOF= ledipasvir-sofosbuvir

Drug Dosing
Ledipasvir-sofosbuvir (90/400 mg): fixed dose combination; one pill once daily
GS-9669: 500 mg once daily
GS-9451: 80 mg once daily

Source: Kohli A, et al. 21st CROI. 2014:Abstract 27LB.

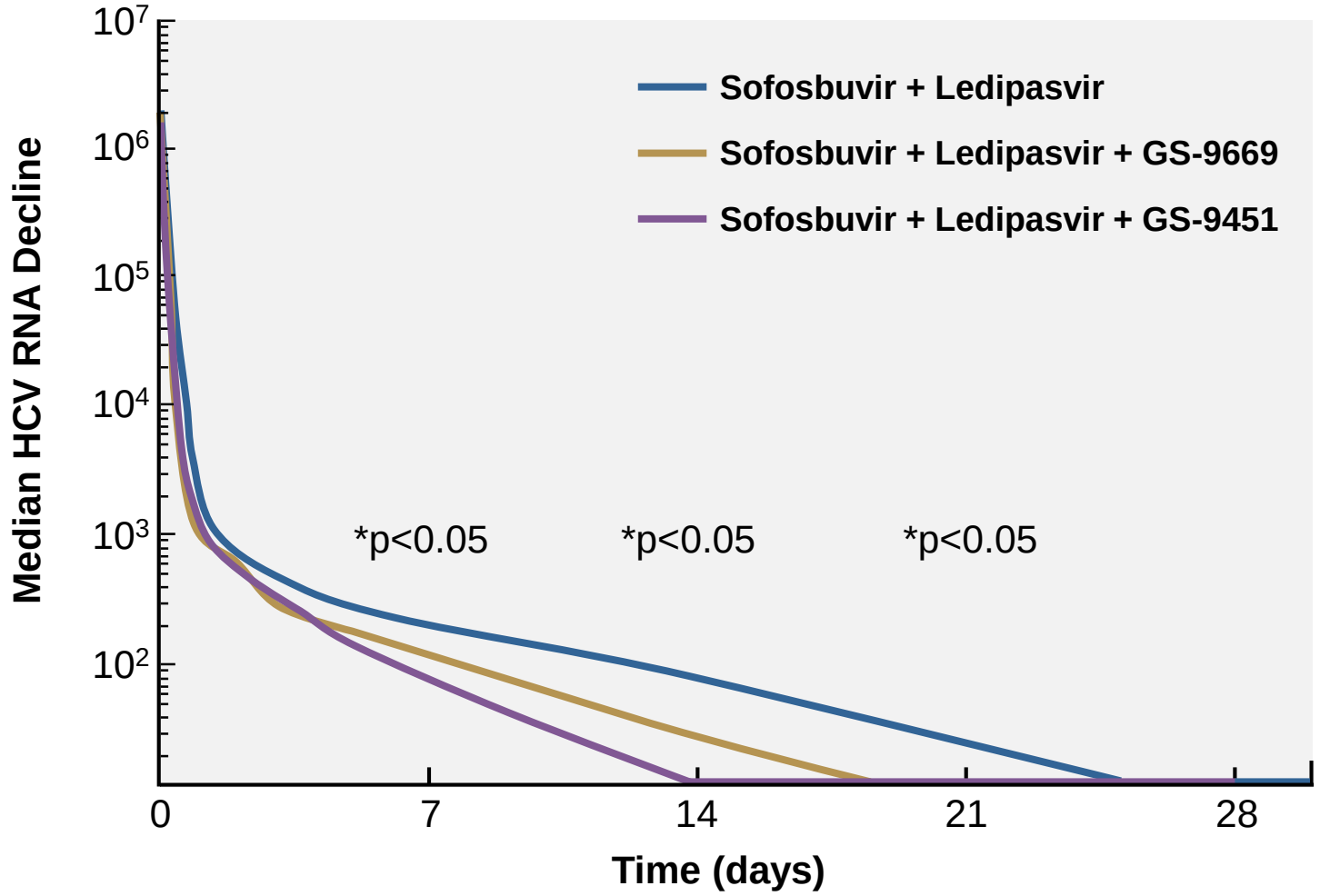
Ledipasvir-Sofosbuvir +/- [GS-9669 or GS-9451] in Naïve GT1 SYNERGY Trial: Participants

Baseline Characteristic	LDV-SOF x 12 weeks (n=20)	LDV-SOF + GS-9669 x 6 weeks (n=20)	LDV-SOF + GS-9451 x 6 weeks (n=20)
Age, mean	57	54	54
Male, %	70	65	80
Black, %	80	95	90
HCV genotype, %			
1A	55	70	85
1B	45	30	15
IL28B CT/TT, %	75	90	75
Advanced fibrosis, %			
Knodell score 3	25	25	25
Knodell score 4	15	0	0

Source: Kohli A, et al. 21st CROI. 2014:Abstract 27LB.

Hepatitis web study

Ledipasvir-Sofosbuvir +/- [GS-9669 or GS-9451] in Naïve GT1
SYNERGY Trial: Viral Kinetics

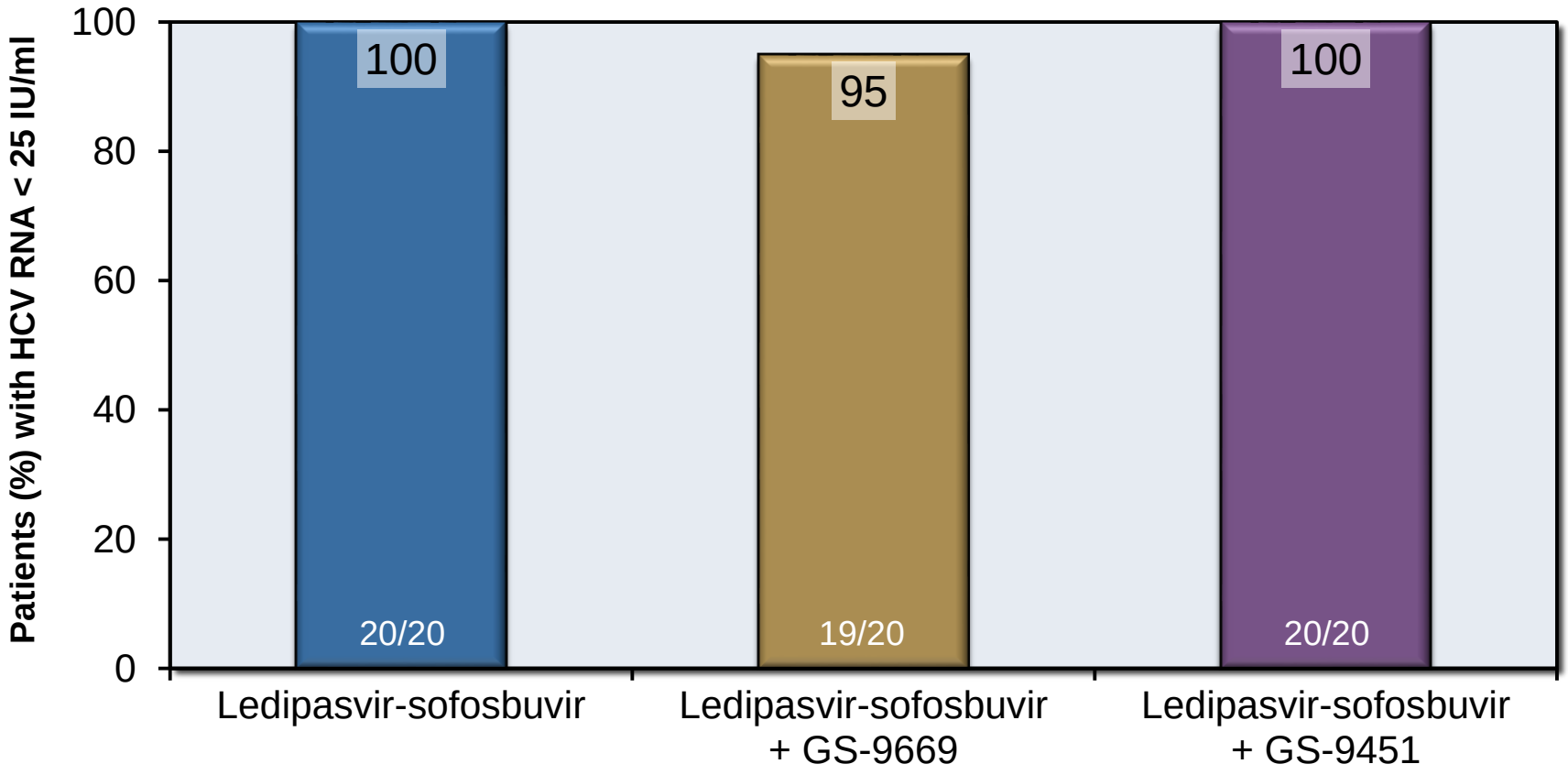


Source: Kohli A, et al. 21st CROI. 2014:Abstract 27LB.

Hepatitis web study

Ledipasvir-Sofosbuvir +/- [GS-9669 or GS-9451] in Naïve GT1 NIH SYNERGY Trial: Features

NIH SYNERGY: SVR 12 by Treatment Regimen



Source: Kohli A, et al. 21st CROI. 2014:Abstract 27LB.

Hepatitis web study

Treatment Naïve and Treatment Experienced

Sofosbuvir + (Ledipasvir or GS-9669) +/- Ribavirin in GT-1
ELECTRON Trial (Arms 12-17 & 22)

Source: Gane EJ, et al. Gastroenterogy. 2014:146:736-43.

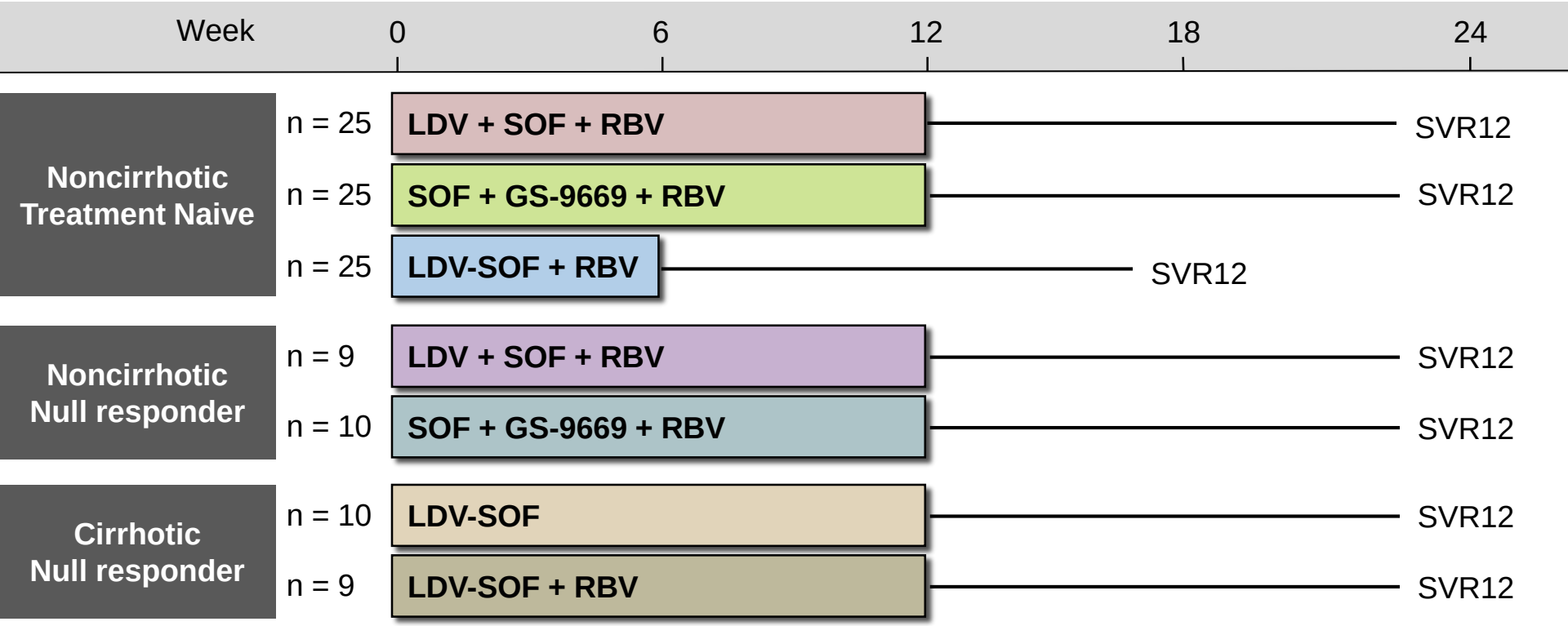
Sofosbuvir + (Ledipasvir or GS-9669) +/- Ribavirin in GT1 ELECTRON Trial (Arms 12-17 & 22): Features

ELECTRON Trial (Arms 12-17 & 22)

- **Design**: Open-label, phase 2, using sofosbuvir plus [ledipasvir or GS-9669 a nonnucleoside polymerase inhibitor] with or without ribavirin in treatment-naïve and treatment-experienced GT1
- **Setting**: two hepatitis treatment centers in New Zealand
- **Entry Criteria**
  - Chronic HCV Genotype 1
  - HCV RNA > 50,000 IU/mL
  - Age > 18
- **Patient Characteristics (range in different treatment arms)**
  - N = 113 patients enrolled
  - Three of seven groups were treatment naïve
  - Four of seven groups were treatment experienced with prior null response
  - Two groups of seven groups were treatment experienced and cirrhotic
  - Three treatment arms used fixed dose ledipasvir-sofosbuvir
- **Primary End-Point**: SVR12

Source: Gane EJ, et al. Gastroenterogy. 2014:146:736-43.

Sofosbuvir + (Ledipasvir or GS-9669 nonNuc Pol Inh) +/- Ribavirin in GT1
ELECTRON Trial Arms (12-17 & 22): Design



Abbreviations: LDV= ledipasvir; SOF = sofosbuvir; RBV = ribavirin

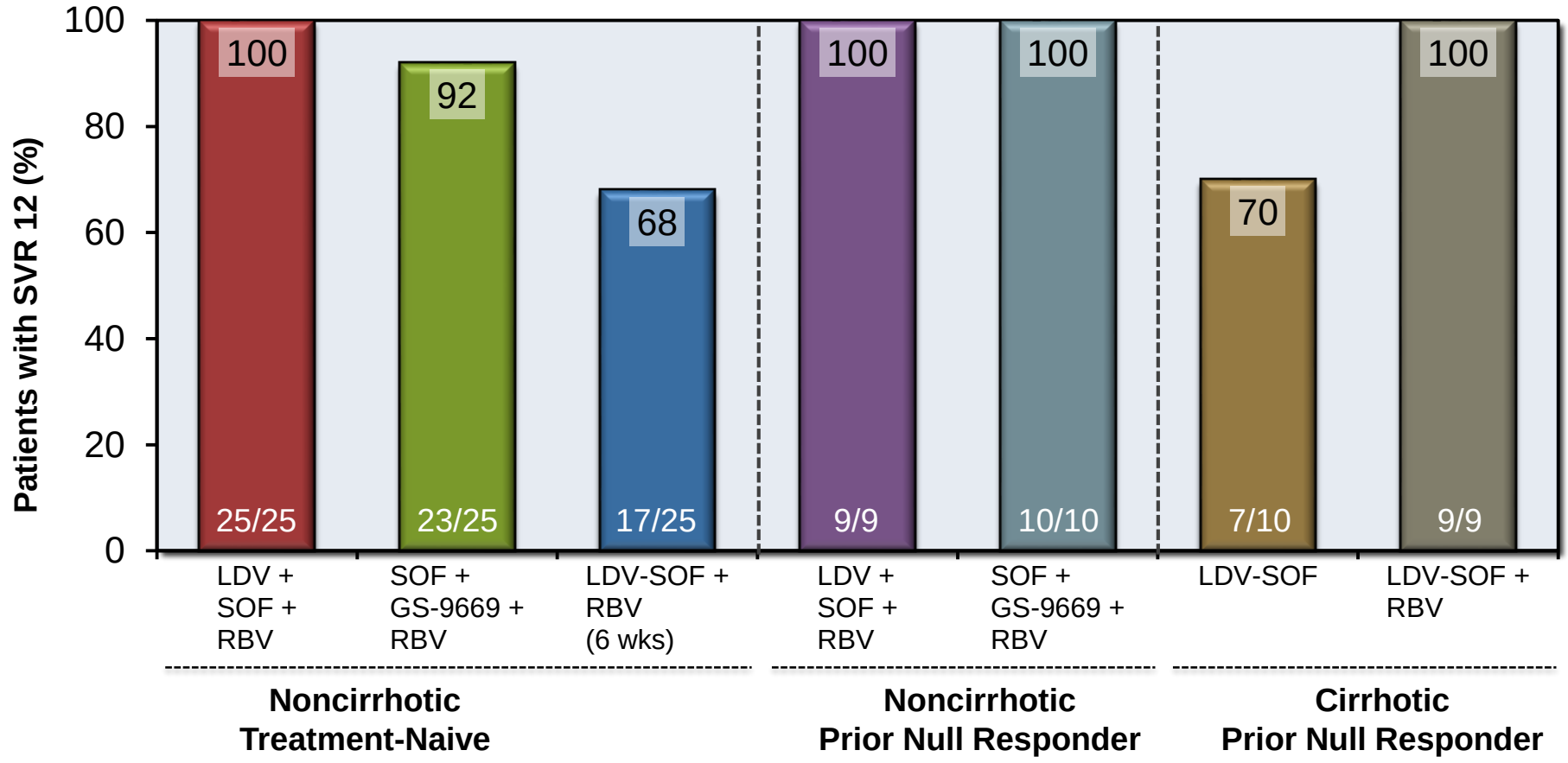
Drug Dosing

Sofosbuvir: 400 mg once daily; Ledipasvir: 90 mg once daily; GS-9669 = 500 mg once daily
Ledipasvir-sofosbuvir (90/400 mg): fixed dose combination one pill once daily
Ribavirin (weight-based and divided bid): 1000 mg/day if < 75kg or 1200 mg/day if ≥ 75kg

Source: Gane EJ, et al. Gastroenterology. 2014:146:736-43.

Sofosbuvir + (Ledipasvir or GS-9669) +/- Ribavirin in GT1 ELECTRON Trial (Arms 12-17 & 22): Results

ELECTRON TRIAL, SVR 12 by Treatment Regimen



*All regimens 12 weeks except treatment-naïve LDV-SOF + Ribavirin= 6 week regimen

Source: Gane EJ, et al. Gastroenterogy. 2014:146:736-43.

Treatment Naïve and Treatment Experienced

Ledipasvir + Sofosbuvir +/- Ribavirin in GT 1 & 3

ELECTRON 2

Source: Gane EJ, et al. 49th EASL. 2014: Abstract O6.

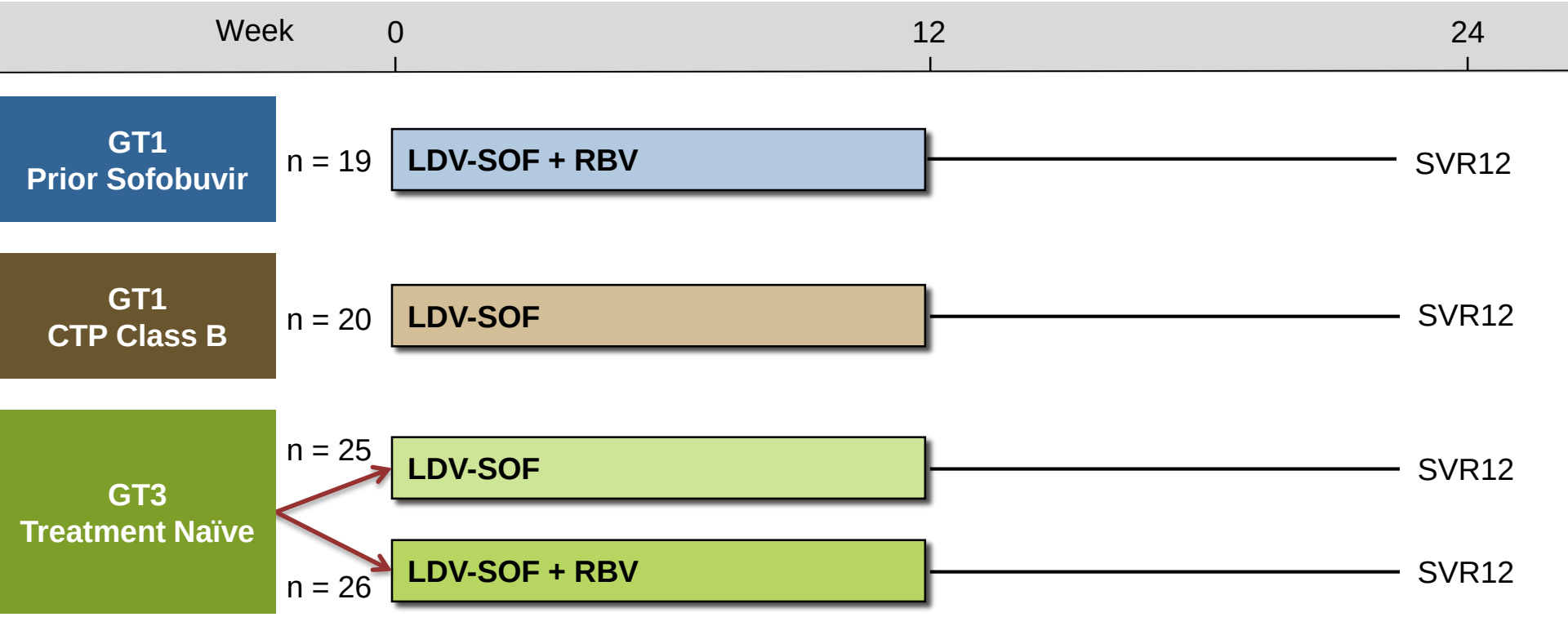
Sofosbuvir-Ledipasvir +/- Ribavirin in GT 1 & 3
ELECTRON 2 Trial: Features

ELECTRON 2 Trial

- **Design**: Open-label, phase 2, using fixed-dose combination of ledipasvir-sofosbuvir +/- ribavirin in treatment-naïve and treatment-experienced genotype 1 and in treatment-naïve genotype 3
- **Setting**: Hepatitis treatment centers in New Zealand
- **Entry Criteria**
  - Chronic HCV (n=90)
  - Group 1: GT1, prior failure with sofosbuvir-based regimen (all relapse)
  - Group 2: GT1, decompensated cirrhosis (Child-Turcotte-Pugh class B)
  - Group 3: GT3, treatment naïve
- **Primary End-Point**: SVR12

Source: Gane EJ, et al. 49th EASL. 2014: Abstract O6.

Sofosbuvir-Ledipasvir +/- Ribavirin in GT 1 & 3
ELECTRON 2: Study Design



Abbreviations: LDV-SOF = ledipasvir-sofosbuvir; RBV = ribavirin

Drug Dosing

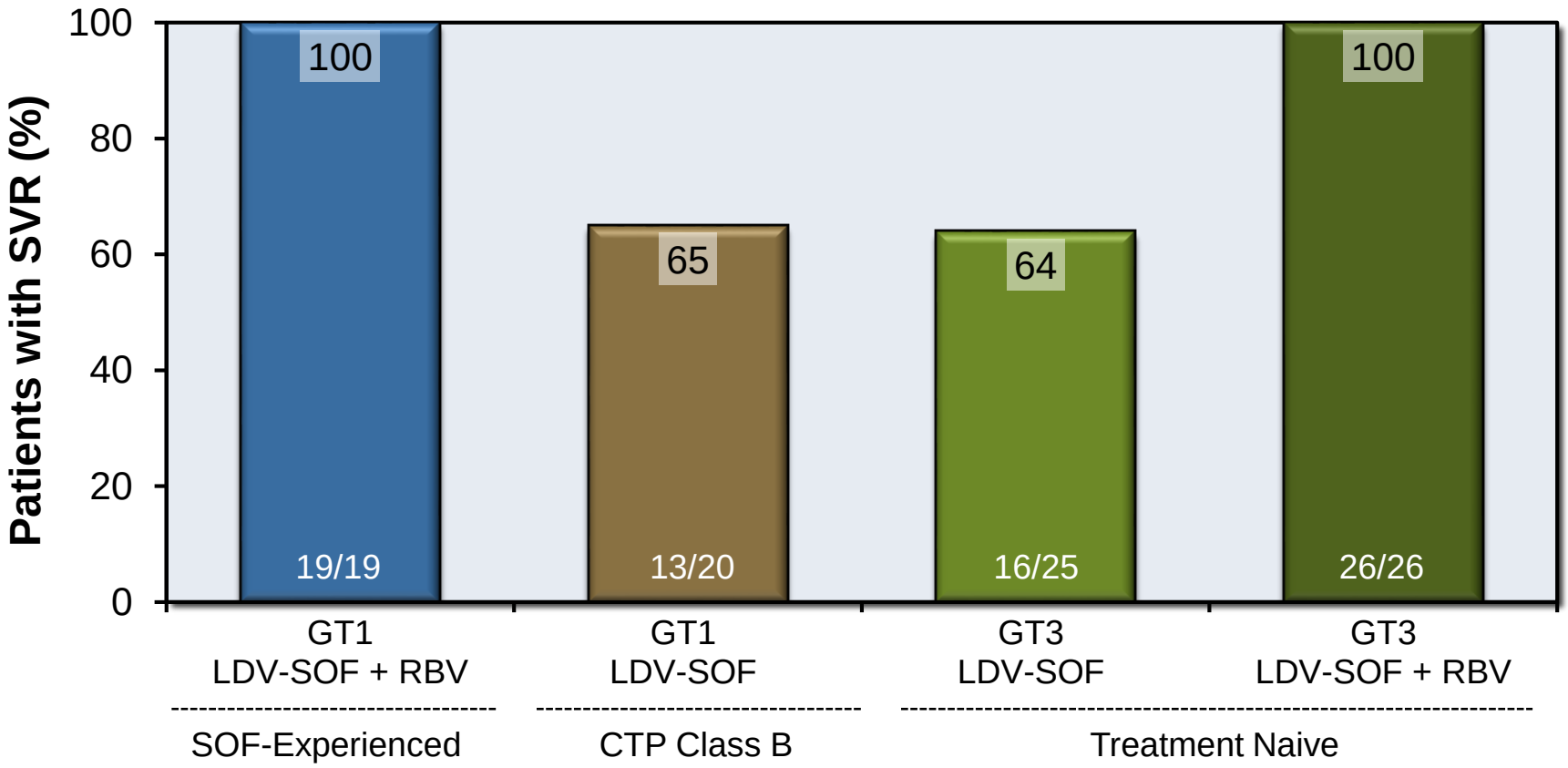
Ledipasvir-sofosbuvir (90/400 mg): fixed dose combination; one pill once daily

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

Source: Gane EJ, et al. 49th EASL. 2014: Abstract O6.

Sofosbuvir-Ledipasvir +/- Ribavirin in GT 1 & 3
ELECTRON 2: Results

SVR 12, by GT and Treatment Regimen



LDV-SOF = ledipasvir-sofosbuvir; RBV = ribavirin

Source: Gane EJ, et al. 49th EASL. 2014: Abstract O6.

Treatment Naïve and Treatment Experienced

HIV Coinfection

Ledipasvir-Sofosbuvir in GT-1 and HIV Coinfection
ERADICATE Trial

Source: Osinusi A, et al. 49th EASL. 2014: Abstract O14.

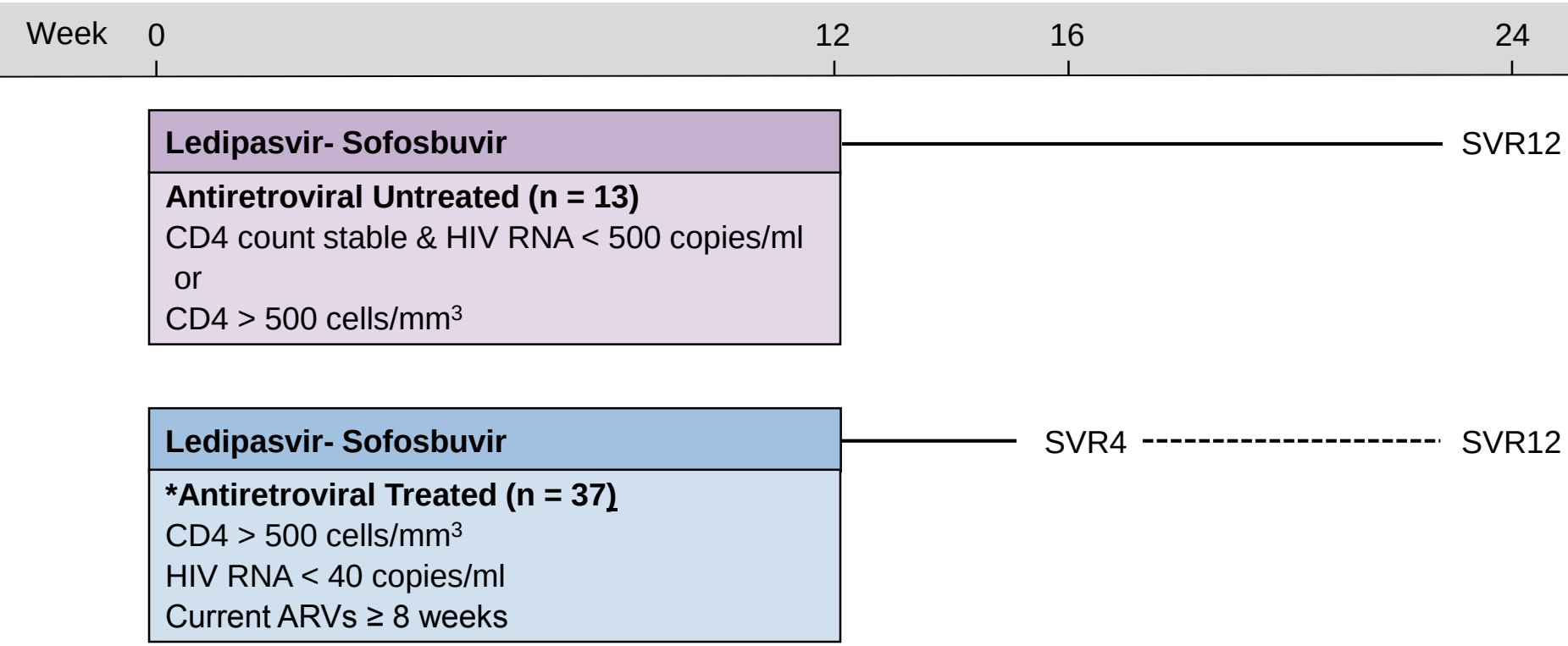
Ledipasvir-Sofosbuvir in GT1 with HIV Coinfection
ERADICATE Trial: Features

NIH ERADICATE Trial

- **Design**: Open-label, phase 2, using fixed dose combination of ledipasvir-sofosbuvir for 12 weeks in treatment-naïve GT 1 and HIV coinfection
- **Setting**: one center in United States
- **Entry Criteria**
  - Chronic HCV Genotype 1
  - HCV Treatment Naïve
- **Patient Characteristics (range in different treatment arms)**
  - N = 50 adult patients
  - Cohort A: Antiretroviral Untreated
  - Cohort B: Antiretroviral Treated
  - Fibrosis stage 0-3 (patients with cirrhosis excluded)
- **End-Points**: Primary = SVR12; safety and tolerability

Source: Osinusi A, et al. 49th EASL. 2014: Abstract O14.

Ledipasvir-Sofosbuvir in GT1 with HIV Coinfection
ERADICATE Trial: Study Design



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

***Antiretrovirals allowed**: tenofovir, emtricitabine, efavirenz, rilpivirine, and raltegravir

Source: Osinusi A, et al. 49th EASL. 2014: Abstract .

Ledipasvir-Sofosbuvir in GT1 with HIV Coinfection ERADICATE Trial: Antiretroviral Regimens

Antiretroviral Agent	Antiretroviral Treated (n = 37)
Tenofovir-emtricitabine	37 (100)
Efavirenz	15 (41)
Raltegravir	10 (27)
Rilpivirine	8 (21)
Rilpivirine + Raltegravir	3 (8)
Efavirenz + Raltegravir	1 (3)

Source: Osinusi A, et al. 49th EASL. 2014: Abstract O14.

Sofosbuvir-Ledipasvir in GT1 with HIV Coinfection ERADICATE Trial: Results

HCV RNA < LLOQ, %	ARV Untreated (n=13)	ARV Treated (n=37)
Week 4	100 (n =13)	100 (n=37)
Week 8	100 (n =13)	100 (n=37))
Week 12 (EOT)	100 (n =13)	100 (n=30)
SVR 4	100 (n =12)	100 (n=20)
SVR 8	100 (n =10)	Not available
SVR 12	100 (n =10)	Not available

Source: Osinusi A, et al. 49th EASL. 2014: Abstract O14.

Summary

Ledipasvir-Sofosbuvir (*Harvoni*) Summary

- Extremely attractive new option for Genotype 1 HCV
- First FDA-approved interferon and ribavirin free regimen
- Highly effective with SVR rates >95%
- Convenient (one pill once a day) and well tolerated
- Few major drug-drug interactions
- Duration 8-24 weeks (depending on treatment experience and presence of cirrhosis, and viral load at baseline)
- Not currently approved for HIV coinfection or other genotypes
- Cost will be major issue, especially if over 12 weeks of Rx
- No resistance testing advised

Ledipasvir-Sofosbuvir (*Harvoni*)
Who to treat for 8 weeks?

- Genotype 1
- Viral Load < 6M
- Noncirrhotic
- Treatment Naïve
- No ribavirin needed for any patient group (with possible exception of special populations – see New Zealand Study)
  - No ribavirin for 8 week treatment

Ledipasvir-Sofosbuvir (*Harvoni*) Potential Off-Label and Future Use

- HIV Coinfection
- Decompensated cirrhosis
- Genotype ?2, 3, ?4-6 with or without ribavirin
- Renal disease with GFR < 30 mL/min
- Interferon to shorten therapy to <8 weeks may be explored post marketing of these medications
- Response guided therapy with VL at times < 1 week?

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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Hepatitis web study