

HEPATITIS WEB STUDY  HEPATITIS C ONLINE

# Ombitasvir-Paritaprevir-Ritonavir + Dasabuvir (*Viekira Pak*)

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OMBITASVIR-PARITAPREVIR-RITONAVIR + DASABUVIR  
**Background and Dosing**

# Ombitasvir-Paritaprevir-Ritonavir + Dasabuvir (*Viekira Pak*)

- **Approval Status:** FDA approval on December 19, 2014
- **Indication:** Genotype 1 chronic HCV infection, including compensated cirrhosis
- **Class & Mechanism**
  - Ombitasvir (ABT-267): NS5A inhibitor
  - Paritaprevir (ABT-450): NS3/4A serine protease inhibitor
  - Ritonavir: HIV protease inhibitor used as pharmacologic booster
  - Dasabuvir (ABT-333): Non-nucleoside NS5B polymerase inhibitor
- **Tablets:** Ombitasvir-Paritaprevir-Ritonavir (fixed dose 12.5/75/50 mg)  
Dasabuvir: 250 mg
- **Dose:** 2 tablets Ombitasvir-Paritaprevir-Ritonavir once daily (am) with food plus Dasabuvir 1 tablet twice daily with food
- **Adverse Effects (AE):** fatigue, pruritus, and insomnia
- **Cost:** \$83,319 for 12-week course

# Ombitasvir-Paritaprevir-Ritonavir + Dasabuvir (*Viekira Pak*) Indications and Usage

Patient Populations	Treatment*	Duration
GT1a, without cirrhosis	Ombitasvir-Paritaprevir-Ritonavir + Dasabuvir + Ribavirin	12 weeks
GT1a, with cirrhosis	Ombitasvir-Paritaprevir-Ritonavir + Dasabuvir + Ribavirin	24 weeks**
GT1b, without cirrhosis	Ombitasvir-Paritaprevir-Ritonavir + Dasabuvir	12 weeks
GT1b, with cirrhosis	Ombitasvir-Paritaprevir-Ritonavir + Dasabuvir + Ribavirin	12 weeks

\*Follow the genotype 1a dosing recommendations in patients with an unknown genotype 1 subtype or with mixed genotype 1 infection.

\*\*Ombitasvir-Paritaprevir-Ritonavir + Dasabuvir + ribavirin for 12 weeks may be considered for some patients based on prior treatment history

# Ombitasvir-Paritaprevir-Ritonavir + Dasabuvir (*Viekira Pak*) Contraindications

- Decompensated cirrhosis
- Concomitantly taking medications that are:
  - highly dependent on CYP3A for clearance,
  - strong inducers of CYP3A and CYP2C8, or
  - strong inhibitors of CYP2C8
- Known hypersensitivity to ritonavir

# Ombitasvir-Paritaprevir-Ritonavir + Dasabuvir (*Viekira Pak*) Estimated Medication Cost for Therapy

Estimated Cost of Ombitasvir-Paritaprevir-Ritonavir + Dasabuvir	
Duration of Treatment	Estimated Cost*
12 Weeks (without ribavirin)	\$83,319
24 Weeks (without ribavirin)	Unknown

\*Estimated cost based on Wholesaler Acquisition Cost in United States

## Drugs Contraindicated for Use with Ombitasvir-Paritaprevir-Ritonavir + Dasabuvir

Drug Class	Drug(s) within Class that are Contraindicated
Alpha1-adrenoreceptor antagonist	Alfuzosin HCL
Anticonvulsants	Carbamazepine, phenytoin, phenobarbital
Antihyperlipidemic agent	Gemfibrozil
Antimycobacterial	Rifampin
Ergot derivatives	Ergotamine, dihydroergotamine, ergonovine, methylergonovine
Ethinyl estradiol-containing products	Ethinyl estradiol-containing medications such as combined oral contraceptives
Herbal Product	St. John's Wort ( <i>Hypericum perforatum</i> )
HMG-CoA Reductase	Lovastatin, simvastatin
Neuroleptics	Pimozide
Non-nucleoside reverse transcriptase inhibitor	Efavirenz
Phosphodiesterase-5 (PDE5) inhibitor	Sildenafil when dosed as <i>Revatio</i> for the treatment of pulmonary arterial hypertension (PAH)
Sedatives/hypnotics	Triazolam; Orally administered midazolam

## Drugs Contraindicated for Use with Ombitasvir-Paritaprevir-Ritonavir + Dasabuvir

Drug Class	Drug(s) within Contraindicated Class	Clinical Comments
Alpha1-adrenoreceptor antagonist	Alfuzosin HCL	Potential for hypotension.
Anticonvulsants	Carbamazepine, phenytoin, phenobarbital	Ombitasvir, paritaprevir, ritonavir and dasabuvir exposures may decrease leading to a potential loss of activity for HCV therapy
Antihyperlipidemic agent	Gemfibrozil	Increase in dasabuvir exposures by 10-fold which may increase the risk of QT prolongation.
Antimycobacterial	Rifampin	Ombitasvir, paritaprevir, ritonavir and dasabuvir exposures may decrease leading to a potential loss of HCV therapeutic activity.
Ergot derivatives	Ergotamine, dihydroergotamine, ergonovine, methylergonovine	Acute ergot toxicity characterized by vasospasm and tissue ischemia has been associated with co-administration of ritonavir and ergonovine, ergotamine, dihydroergotamine, or methylergonovine.
Ethinyl estradiol-containing products	Ethinyl estradiol-containing medications such as combined oral contraceptives	Potential for ALT elevations
Herbal Product	St. John's Wort ( <i>Hypericum perforatum</i> )	Ombitasvir, paritaprevir, ritonavir and dasabuvir exposures may decrease leading to a potential loss of HCV therapeutic activity.
HMG-CoA Reductase	Lovastatin, simvastatin	Potential for myopathy including rhabdomyolysis.
Neuroleptics	Pimozide	Potential for cardiac arrhythmias.
Non-nucleoside reverse transcriptase inhibitor	Efavirenz	Co-administration of efavirenz based regimens with paritaprevir, ritonavir plus dasabuvir was poorly tolerated and resulted in liver enzyme elevations.
Phosphodiesterase-5 (PDE5) inhibitor	Sildenafil when dosed as REVATIO for the treatment of pulmonary arterial hypertension (PAH)	There is increased potential for sildenafil-associated adverse events such as visual disturbances, hypotension, priapism, and syncope.
Sedatives/hypnotics	Triazolam Orally administered midazolam	Triazolam and orally administered midazolam are extensively metabolized by CYP3A4. Coadministration of triazolam or orally administered midazolam with VIEKIRA PAK may cause large increases in the concentration of these benzodiazepines. The potential exists for serious and/or life threatening events such as prolonged or increased sedation or respiratory depression.



## Summary of Key Phase 3 Studies

- **SAPPHIRE-I:** GT1 (a & b), Treatment-Naïve, without cirrhosis  
- Ombitasvir-paritaprevir-ritonavir + dasabuvir + RBV x 12 weeks
- **PEARL-III:** GT1b, Treatment-Naïve, without cirrhosis  
- Ombitasvir-paritaprevir-ritonavir + dasabuvir +/- RBV x 12 weeks
- **PEARL-IV:** GT1a, Treatment-Naïve, without cirrhosis  
- Ombitasvir-paritaprevir-ritonavir + dasabuvir +/- RBV x 12 weeks
- **SAPPHIRE-II:** GT1 (a & b), Treatment-Experienced, without cirrhosis  
- Ombitasvir-paritaprevir-ritonavir + dasabuvir + RBV x 12 weeks
- **PEARL-II:** GT1b, Treatment-Experienced, without cirrhosis  
- Ombitasvir-paritaprevir-ritonavir + dasabuvir +/- RBV x 12 week
- **TURQUOISE II:** GT1 (a & b), Treatment-Naïve & Experienced, with cirrhosis  
- Ombitasvir-paritaprevir-ritonavir + dasabuvir + RBV x 12 or 24 weeks
- **UOISE II:** GT1b, Treatment-Naïve & Experienced, with cirrhosis  
- Ombitasvir-paritaprevir-ritonavir + dasabuvir x 12 weeks

## Summary of Key Studies in Special Populations

- **TURQUOISE-I:** GT1 (a & b), HIV Coinfection, Treatment Naïve/Experienced
  - Ombitasvir-paritaprevir-ritonavir + dasabuvir + RBV x 12 or 24 weeks
- **CORAL-I:** GT1 (a & b), Post-Liver Transplantation Recipients
  - Ombitasvir-paritaprevir-ritonavir + dasabuvir + RBV x 24 weeks

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir in Treatment-Naïve Patients

Treatment Naïve

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + RBV in GT1 SAPPHIRE-I

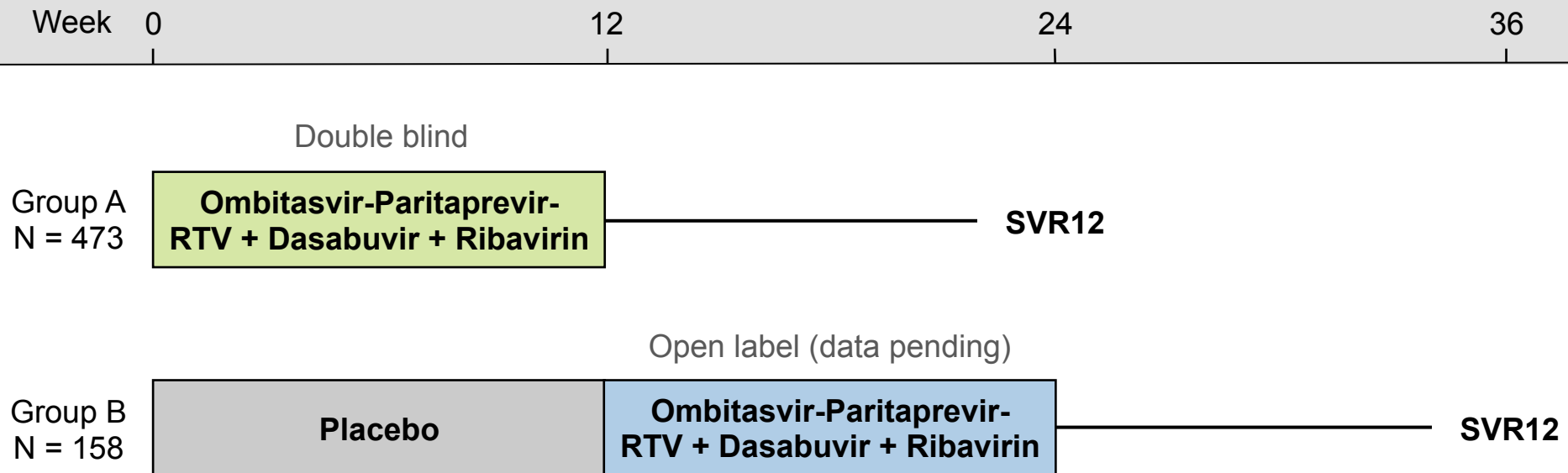
Feld JJ, et al. N Engl J Med. 2014;370:1594-1603.

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + Ribavirin in GT1 SAPPHIRE-I Study: Design

## SAPPHIRE-I: Features

- **Design:** Phase 3, randomized, double-blind, placebo-controlled trial evaluating safety and efficacy of ombitasvir-paritaprevir-ritonavir and dasabuvir + ribavirin for 12 weeks in treatment-naïve patients with chronic hepatitis C virus genotype 1
- **Setting:** International at 79 sites in North America, Europe, and Australia
- **Entry Criteria**
  - Chronic HCV infection with genotype 1a or 1b
  - Treatment-naïve
  - Age 18-70
  - Plasma HCV RNA greater than 10,000 IU/mL
  - Absence of cirrhosis
  - Absence of coinfection with HBV or HIV
- **Primary End-Point:** SVR12

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + Ribavirin in GT1 SAPPHIRE-I Study: Study Regimens



**RTV** = Ritonavir

## Drug Dosing

Ombitasvir-Paritaprevir-Ritonavir (25/150/100 mg once daily) + Dasabuvir: 250 mg twice daily

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

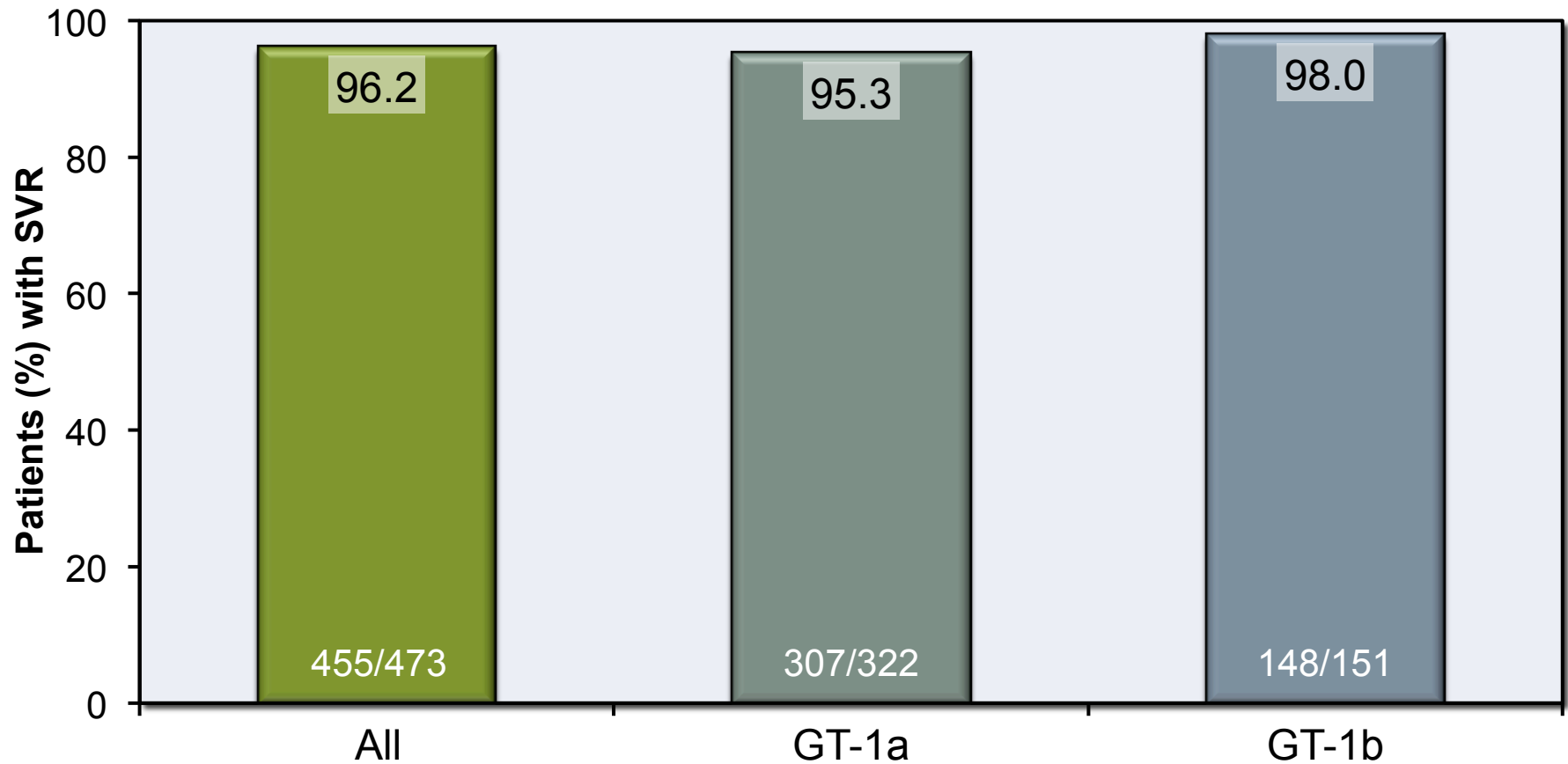
# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + Ribavirin in GT1 SAPPHERE-I Study: Baseline Characteristics

Baseline Characteristic	Group A (N=473)	Group B (N=158)
Age (years), Mean	49.4	51.2
Male sex %	57.3	46.2
Race (%)		
White	90.5	91.1
Black	5.5	5.1
Other	4.0	3.8
Body Mass Index (Mean)	25.7	26.2
HCV genotype (%)		
1a	68.1	66.5
1b	31.9	33.5
IL28B CC genotype, (%)	30.4	31.6
HCV RNA, log <sub>10</sub> IU/ml	6.40	6.47
Fibrosis score ≥ F2	23.3	26.6

Source: Feld JJ, et al. N Engl J Med. 2014;370:1594-1603.

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + Ribavirin in GT1 SAPPHIRE-I Study: Results

SAPPHIRE-I: SVR12 in Group A, by Genotype 1 Subtype

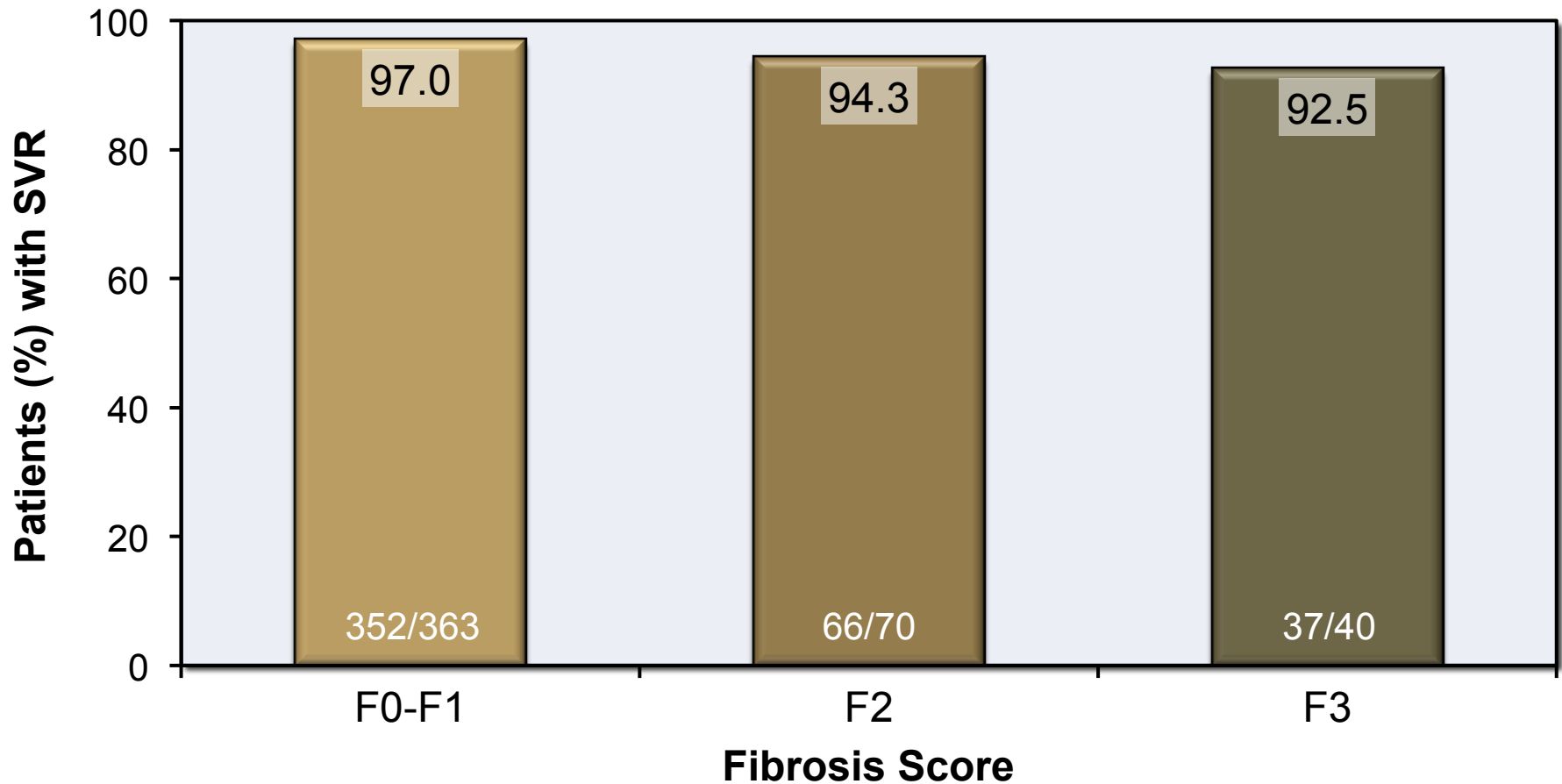


Source: Feld JJ, et al. N Engl J Med. 2014;370:1594-1603.



# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + Ribavirin in GT1 SAPPHIRE-I Study: Results

SAPPHIRE-I: SVR12 in Group A, Fibrosis Score



Source: Feld JJ, et al. N Engl J Med. 2014;370:1594-1603.

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + Ribavirin in GT1 SAPPHIRE-I Study: Adverse Events During Double-Blind Phase

Event	Group A = 3D + RBV (N=473)	Group B = Placebo (N=158)
Any adverse event (%)	87.5	73.4
Any adverse event leading to discontinuation of study drug (%)	0.6	0.6
Any serious adverse event (%)	2.1	0
Grade 3 or 4 lab abnormality (%)		
Alanine aminotransferase	0.9	4.4
Aspartate aminotransferase	0.6	1.9
Alkaline phosphatase	0	0
Total bilirubin	2.8	0
Hemoglobin	0	0

**3D** = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir; **RBV** = Ribavirin

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + Ribavirin in GT1 SAPPHIRE-I Study: Conclusions

**Conclusions:** “In previously untreated patients with HCV genotype 1 infection and no cirrhosis, a 12-week multitargeted regimen of ABT-450/r–ombitasvir and dasabuvir with ribavirin was highly effective and was associated with a low rate of treatment discontinuation.”

**Note:** ABT-450/r = Paritaprevir-Ritonavir

Treatment Naïve

Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir +/- RBV in GT1  
**PEARL-III and PEARL-IV**

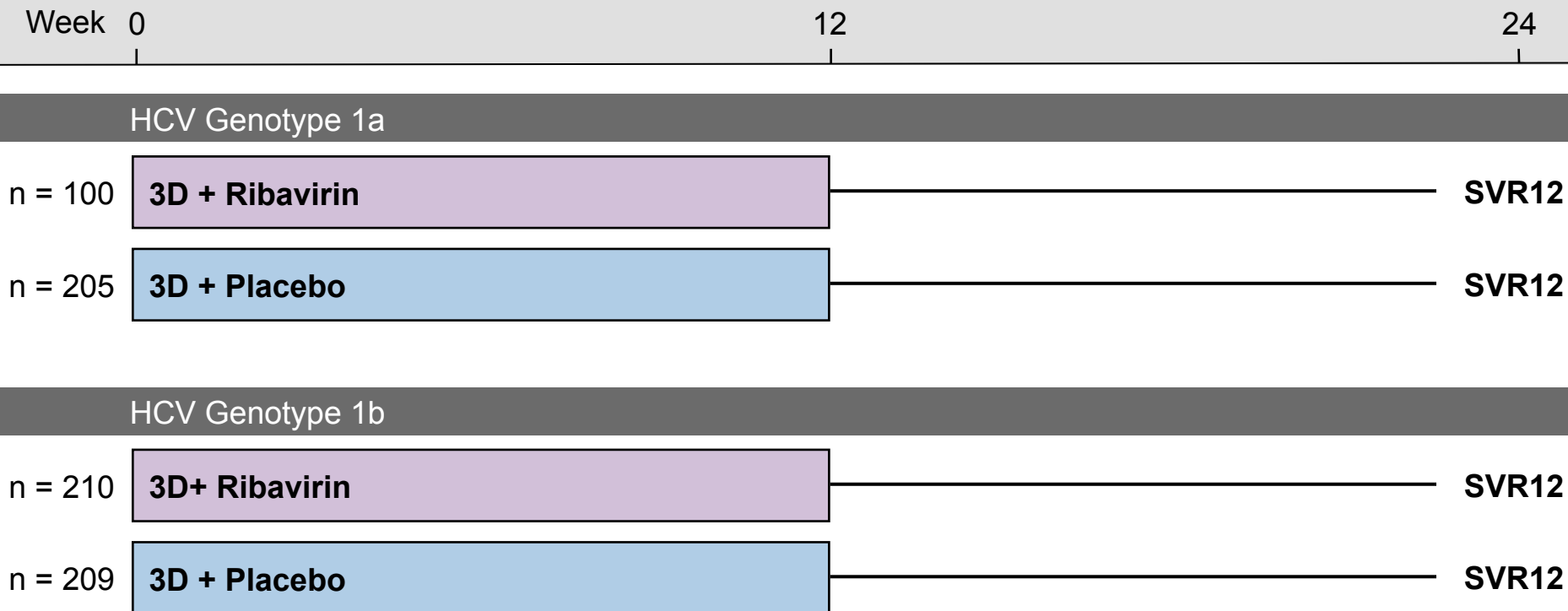
Ferenci P, et al. N Engl J Med. 2014;370:1983-92.

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir +/- RBV in GT1 PEARL-III and PEARL-IV: Study Design

## PEARL-III and PEARL-IV: Features

- **Design:** Two phase 3, randomized, open-label trials evaluating safety and efficacy of ombitasvir-paritaprevir-ritonavir + dasabuvir +/- ribavirin for 12 weeks in treatment-naïve patients with chronic HCV GT 1b (PEARL-III) or 1a (PEARL-IV)
- **Setting:** International (PEARL-III at 53 sites and PEARL-IV at 50 sites)
- **Entry Criteria**
  - Chronic HCV infection with genotype 1a or 1b
  - Treatment-naïve
  - Age 18-70
  - Plasma HCV RNA greater than 10,000 IU/mL
  - Absence of cirrhosis
  - Absence of coinfection with HBV or HIV
- **Primary End-Point:** SVR12

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir +/- RBV in GT1 PEARL-III and PEARL-IV: Study Regimens



**3D** = Ombitasvir-Paritaprevir-Ritonavir + Dasabuvir

## Drug Dosing

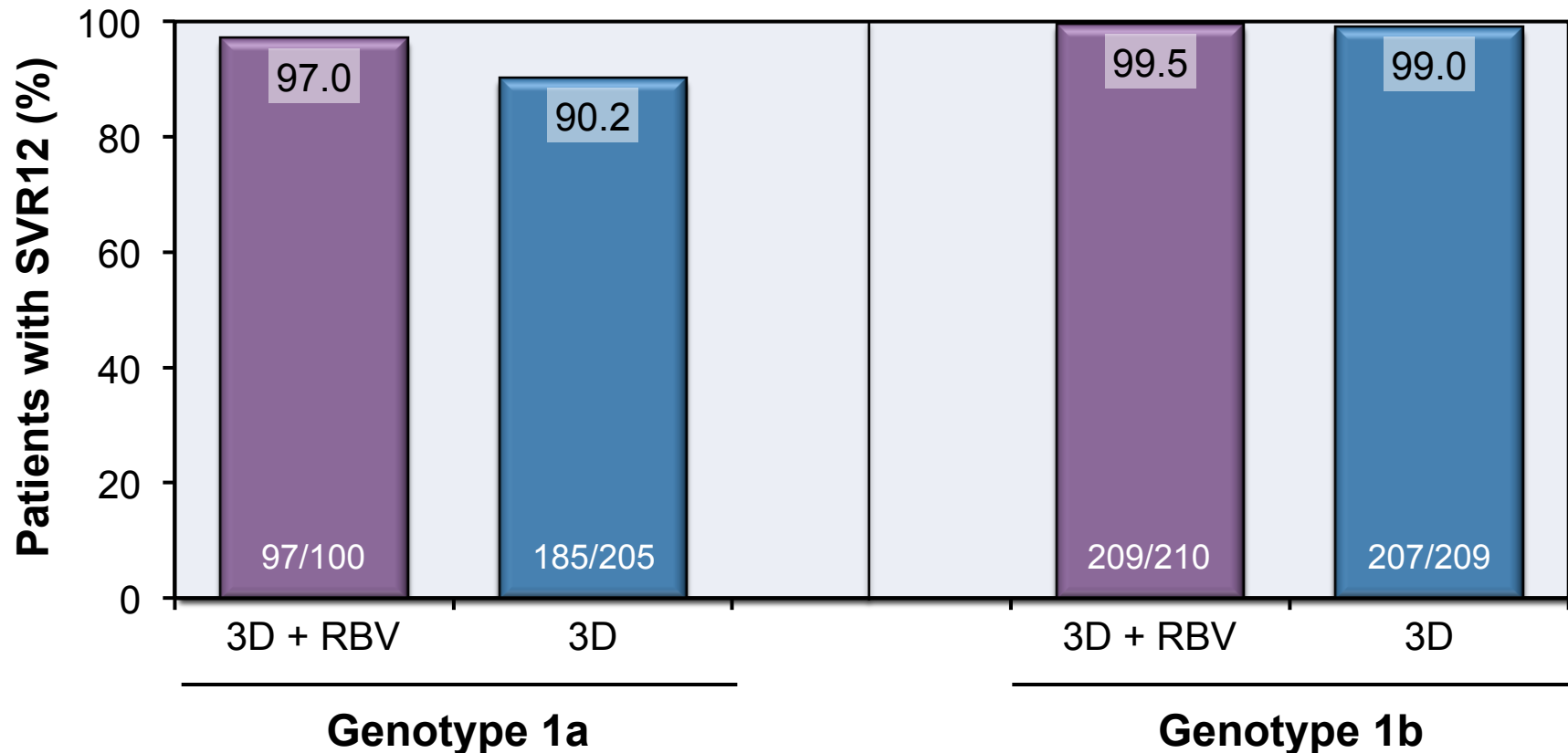
3D = Ombitasvir-Paritaprevir-Ritonavir (25/150/100 mg once daily) + Dasabuvir: 250 mg twice daily  
Ribavirin (RBV): weight-based and divided bid (1000 mg/day if < 75kg or 1200 mg/day if ≥ 75kg)

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir +/- RBV in GT1 PEARL-III and PEARL-IV: Baseline Characteristics

Baseline Characteristic	Genotype 1a		Genotype 1b	
	3D + RBV (n=100)	3D (n=205)	3D + RBV (n=210)	3D (n=209)
Age, years	51.6	51.4	48.4	49.2
Male sex (%)	70.0	62.9	50.5	41.2
BMI kg/m <sup>2</sup>	26.9	26.7	25.8	26.1
Race (%)				
White	86.0	83.4	94.3	94.2
Black	10.0	12.7	4.8	4.8
Other	4.0	3.9	1.0	1.0
IL28B CC (%)	31.0	30.7	21.0	21.1
Metavir F3 (%)	16.0%	18.5%	10.5%	9.6%
HCV RNA log <sub>10</sub> IU/ml	6.64	6.53	6.29	6.33
<b>3D</b> = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir; <b>RBV</b> = Ribavirin				

Source: Ferenci P, et al. N Engl J Med. 2014;370:1983-92.

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir +/- RBV in GT1 PEARL-III and PEARL-IV: Results



3D = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir  
RBV = Ribavirin

Source: Ferenci P, et al. N Engl J Med. 2014;370:1983-92.



# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir +/- RBV in GT1 PEARL-III and PEARL-IV: Adverse Events

Event	GT1a		GT1b	
	3D + RBV (n=100)	3D (n=205)	3D + RBV (n=210)	3D (n=209)
Any adverse event %	92.0	82.4	80.0	67
Any serious adverse event %	3.0	0.5	1.9	1.9
Common adverse events:				
Headache %	25.0	28.3	24.3	23.4
Fatigue %	46.0	35.1	21.4	23.0
Pruritus %	10.0	5.9	11.9	5.3
Nausea %	21.0	13.7	11.0	4.3
Insomnia %	17.0	7.8	9.0	3.3
Diarrhea %	14.0	16.1	4.3	6.2
Laboratory abnormalities (%):				
Hemoglobin < 10 g/dl	4.0	0	9.0	0
Total bilirubin > 3x ULN	3.0	0.5	5.7	0.5

**3D** = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir; **RBV** = Ribavirin

Source: Ferenci P, et al. N Engl J Med. 2014;370:1983-92.

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir +/- RBV in GT1 PEARL-III and PEARL-IV: Adverse Events

Event	GT1a		GT1b	
	3D + RBV (n=100)	3D (n=205)	3D + RBV (n=210)	3D (n=209)
Any adverse event %	92.0	82.4	80.0	67
Any serious adverse event %	3.0	0.5	1.9	1.9
Common adverse events:				
Headache %	25.0	28.3	24.3	23.4
Fatigue %	46.0	35.1	21.4	23.0
Pruritus %	10.0	5.9	11.9	5.3
Nausea %	21.0	13.7	11.0	4.3
Insomnia %	17.0	7.8	9.0	3.3
Diarrhea %	14.0	16.1	4.3	6.2
Laboratory abnormalities (%):				
Hemoglobin < 10 g/dl	4.0	0	9.0	0
Total bilirubin > 3x ULN	3.0	0.5	5.7	0.5

**3D** = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir; **RBV** = ribavirin

Source: Ferenci P, et al. N Engl J Med. 2014;370:1983-92.

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir +/- RBV in GT1 PEARL-III and PEARL-IV: Conclusions

**Conclusions:** “Twelve weeks of treatment with ABT-450/r–ombitasvir and dasabuvir without ribavirin was associated with high rates of sustained virologic response among previously untreated patients with HCV genotype 1 infection. Rates of virologic failure were higher without ribavirin than with ribavirin among patients with genotype 1a infection but not among those with genotype 1b infection.”

**Note:** ABT-450/r = Paritaprevir-Ritonavir

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir in Treatment-Experienced Patients

Treatment Experienced

Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + RBV in GT1  
**SAPPHIRE-II**

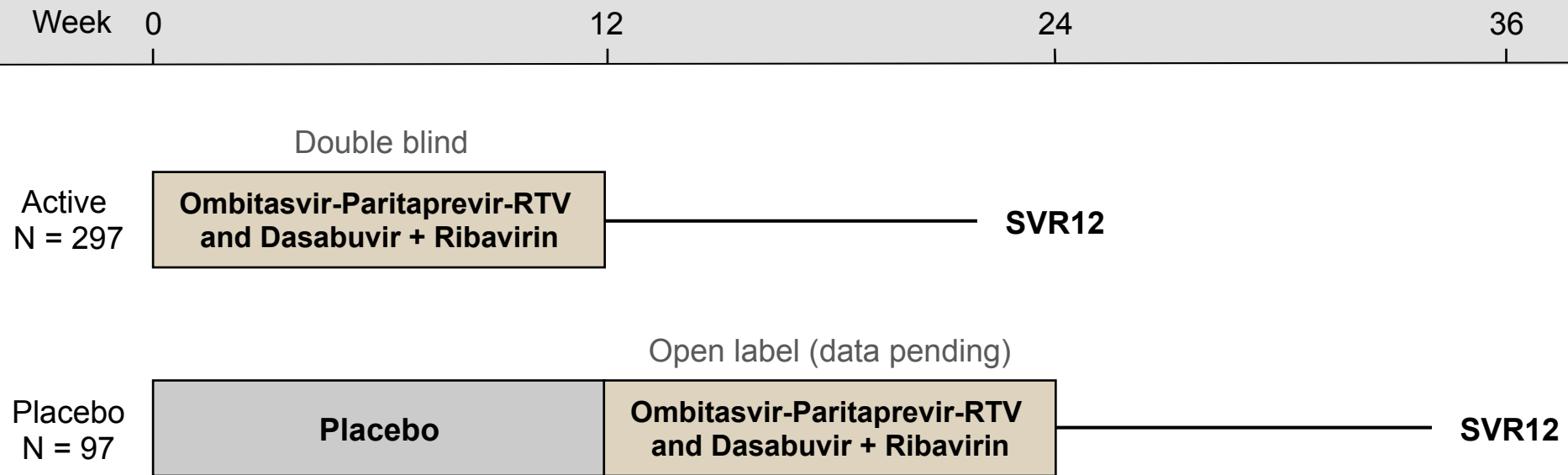
Zeuzem S, et al. N Engl J Med. 2014;370:1604-14.

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + RBV in GT1 SAPPHIRE-II: Study Design

## SAPPHIRE-II: Features

- **Design:** Phase 3, randomized, open-label trial evaluating safety and efficacy of ombitasvir-paritaprevir-ritonavir and dasabuvir + ribavirin for 12 weeks in treatment-experienced patients with chronic HCV genotype 1
- **Setting:** 76 sites in Australia, North America, and Europe
- **Entry Criteria**
  - Chronic HCV infection with genotype 1
  - Prior treatment experience with peginterferon plus ribavirin
  - Age 18-70
  - Plasma HCV RNA greater than 10,000 IU/mL
  - Absence of cirrhosis
  - Absence of coinfection with HBV or HIV
- **Primary End-Point:** SVR12

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + RBV in GT1 SAPPHIRE-II: Regimens



**RTV** = Ritonavir

## Drug Dosing

Ombitasvir-Paritaprevir-Ritonavir (25/150/100 mg once daily) + Dasabuvir: 250 mg twice daily

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

# Ombitasvir-Paritaprevir-Ritonavir + Dasabuvir + RBV in GT1 SAPPHIRE-II Study: Baseline Characteristics

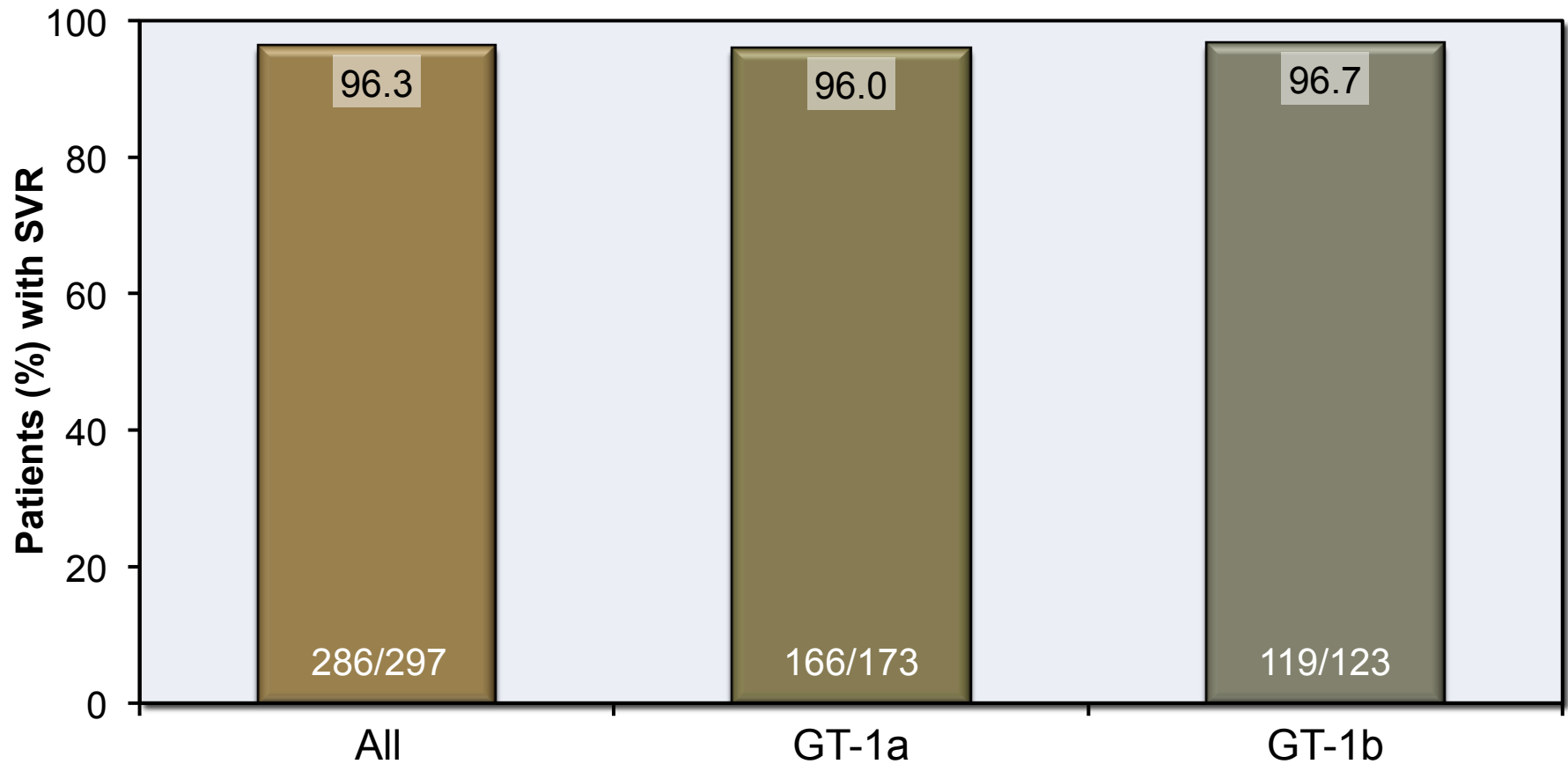
Baseline Characteristic	3D + RBV (n=297)	Placebo Arm (n=97)
Age (years), Mean	51.7	54.9
Male sex %	56.2	61.9
Race (%)		
White	90.6	88.7
Black	7.4	10.3
Asian	2.0	0
Body Mass Index (Mean)	26.3	26.4
HCV genotype (%)		
1a	58.2	58.8
1b	41.4	41.2
IL28B CC genotype, (%)	11.4	7.2
Type of Prior Response		
Relapse	29.0	29.9
Partial Response	21.9	21.6
Null Response	49.2	48.5
HCV RNA, log <sub>10</sub> IU/ml (mean)	6.55	6.52
Fibrosis score F2 or F3 (%)	32.0	33.0
<b>3D</b> = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir; <b>RBV</b> = Ribavirin		

Source: Zeuzem S, et al. N Engl J Med. 2014;370:1604-14.



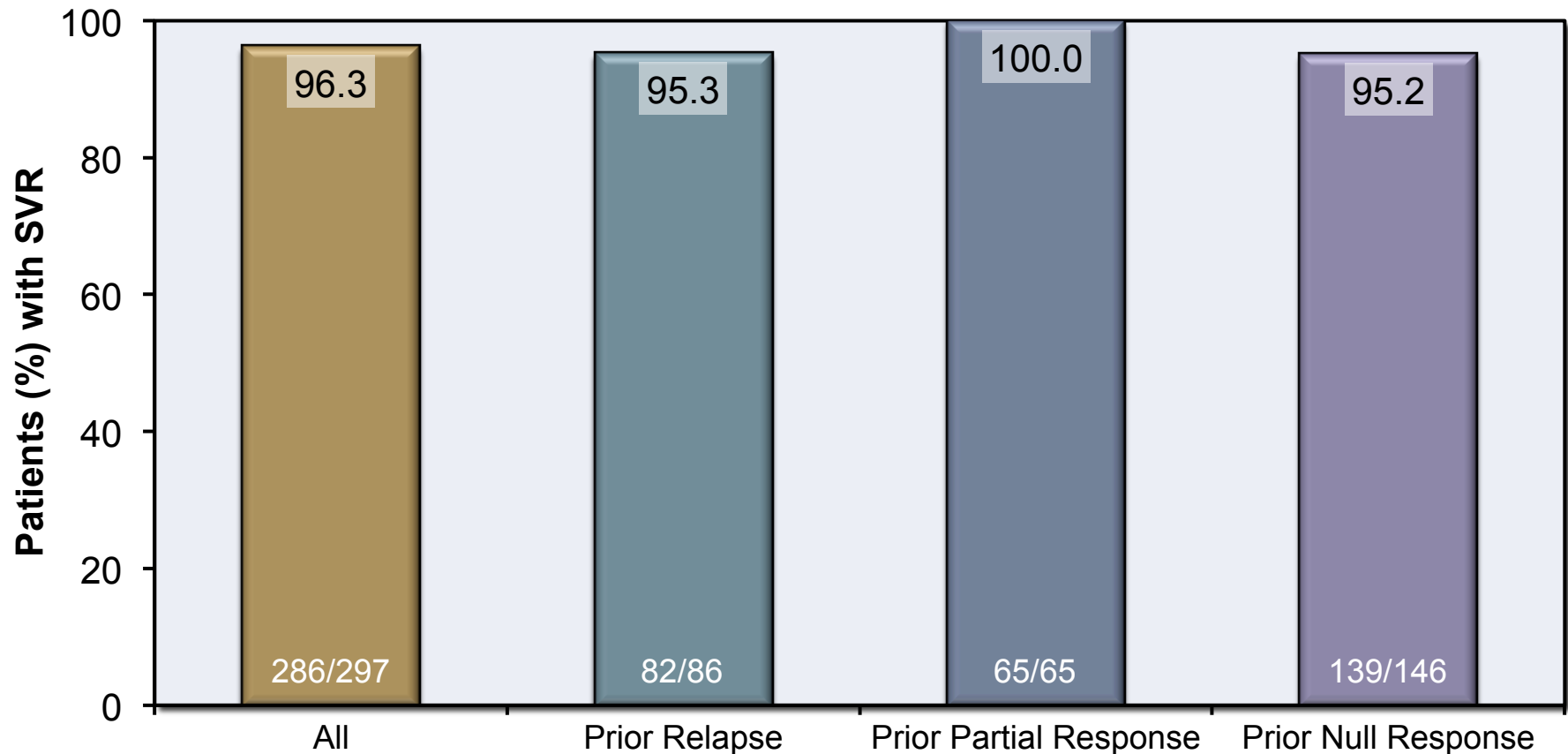
# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + RBV in GT1 SAPPHIRE-II: Results

## SAPPHIRE-II: Results by Genotype 1 Subtype



# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + RBV in GT1 SAPPHERE-II: Results

## SAPPHERE-II: Results by Prior Treatment Response



Source: Zeuzem S, et al. N Engl J Med. 2014;370:1604-14.

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + RBV in GT1 SAPPHERE-II Study: Key Adverse Events

Event	3D + RBV (n=297)	Placebo (n=97)
Any adverse events %	91.2	82.5
Any serious adverse event %	2.0	1.0
Common adverse events:		
Headache %	36.4	35.1
Fatigue %	33.3	22.7
Nausea %	20.2	17.5
Asthenia %	15.8	11.3
Insomnia %	14.1	7.2
Pruritus %	13.8	5.2
Diarrhea %	13.1	12.4
Dyspnea %	12.5	10.3
Cough %	10.8	5.2
Myalgia %	7.7	10.3
Abnormalities in laboratory values of grade 3 or 4 %		
Alanine aminotransferase	1.7	3.1
Total bilirubin	2.4	0

**3D** = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir; **RBV** = Ribavirin

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + RBV in GT1 SAPPHIRE-II: Conclusions

**Conclusions:** “Rates of response to a 12-week interferon-free combination regimen were more than 95% among previously treated patients with HCV genotype 1 infection, including patients with a prior null response.”

Treatment Experienced

Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir +/- RBV in GT1b  
**PEARL-II**

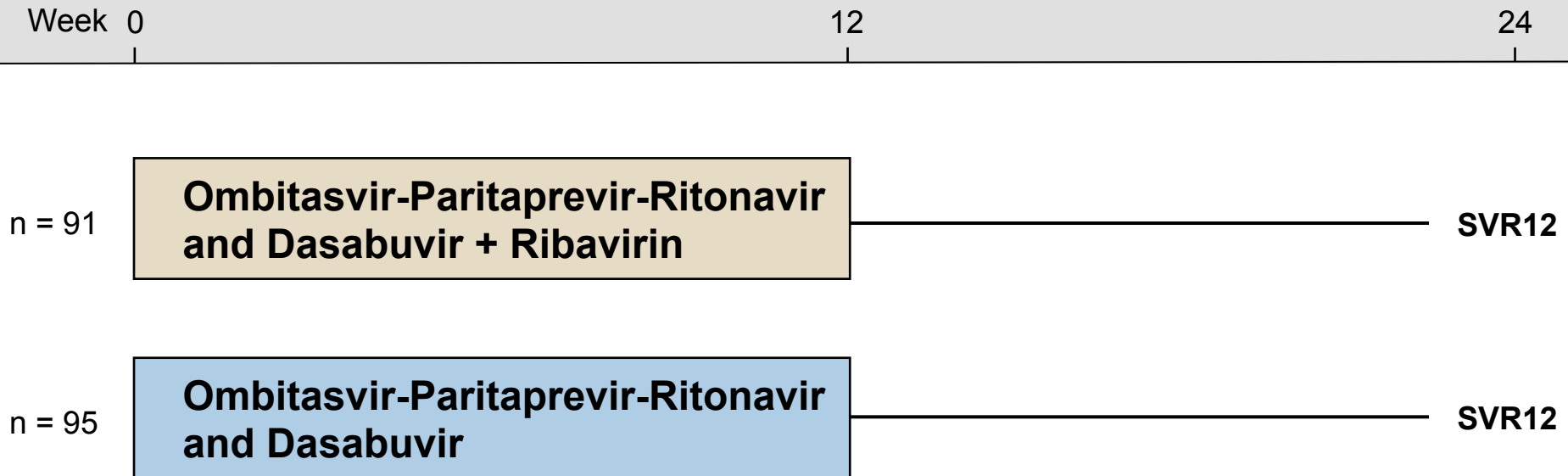
Andreone P, et al. *Gastroenterology*. 2014;147:359-65.

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir +/- RBV in GT1b PEARL-II: Study Design

## PEARL-II: Features

- **Design:** Phase 3, randomized, open-label trial evaluating safety and efficacy of 3D (ombitasvir-paritaprevir-ritonavir + dasabuvir) with or without ribavirin for 12 weeks in treatment-experienced patients with chronic HCV GT 1b
- **Setting:** 43 international sites
- **Entry Criteria**
  - Chronic HCV infection with genotype 1b
  - Prior treatment experience with peginterferon plus ribavirin
  - Age 18-70
  - Plasma HCV RNA greater than 10,000 IU/mL
  - Absence of cirrhosis
  - Absence of coinfection with HBV or HIV
- **Primary End-Point:** SVR12

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir +/- RBV in GT1b PEARL-II: Regimens



**3D** = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir

## Drug Dosing

Ombitasvir-Paritaprevir-Ritonavir (25/150/100 mg once daily) + Dasabuvir: 250 mg twice daily

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

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir +/- RBV in GT1b PEARL-II: Baseline Characteristics

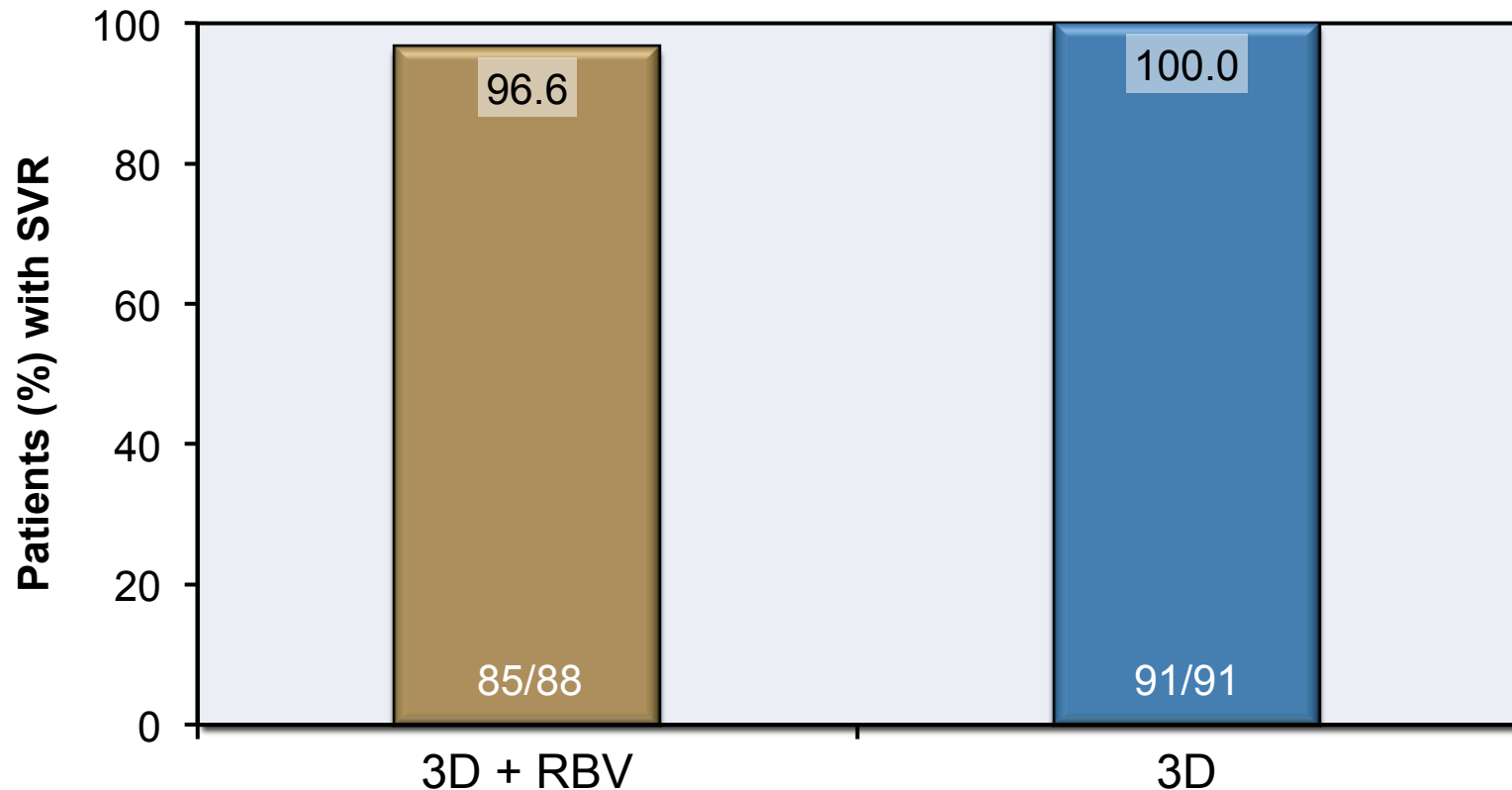
Baseline Characteristic	3D + RBV (n=91)	3D (n=95)
Age (years), Mean	54.2	54.2
Male sex %	49.5	60.0
Race (%)		
White	92.3	90.5
Black	3.4	6.3
Body Mass Index (Mean)	26.2	27.5
Previous Response to PEG + RBV		
Null responder	35.2	34.7
Partial responder	28.6	28.4
Relapser	36.3	36.8
IL28B Non-CC genotype, (%)	89.0	92.6
HCV RNA, log <sub>10</sub> IU/ml (mean)	6.56	6.48
Fibrosis score F3 (%)	15.4	13.7
<b>3D</b> = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir; <b>RBV</b> = Ribavirin		

Source: Andreone P, et al. *Gastroenterology*. 2014;147:359-65.



# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir +/- RBV in GT1b PEARL-II: Results

## PEARL-II: SVR 12 Rates\*



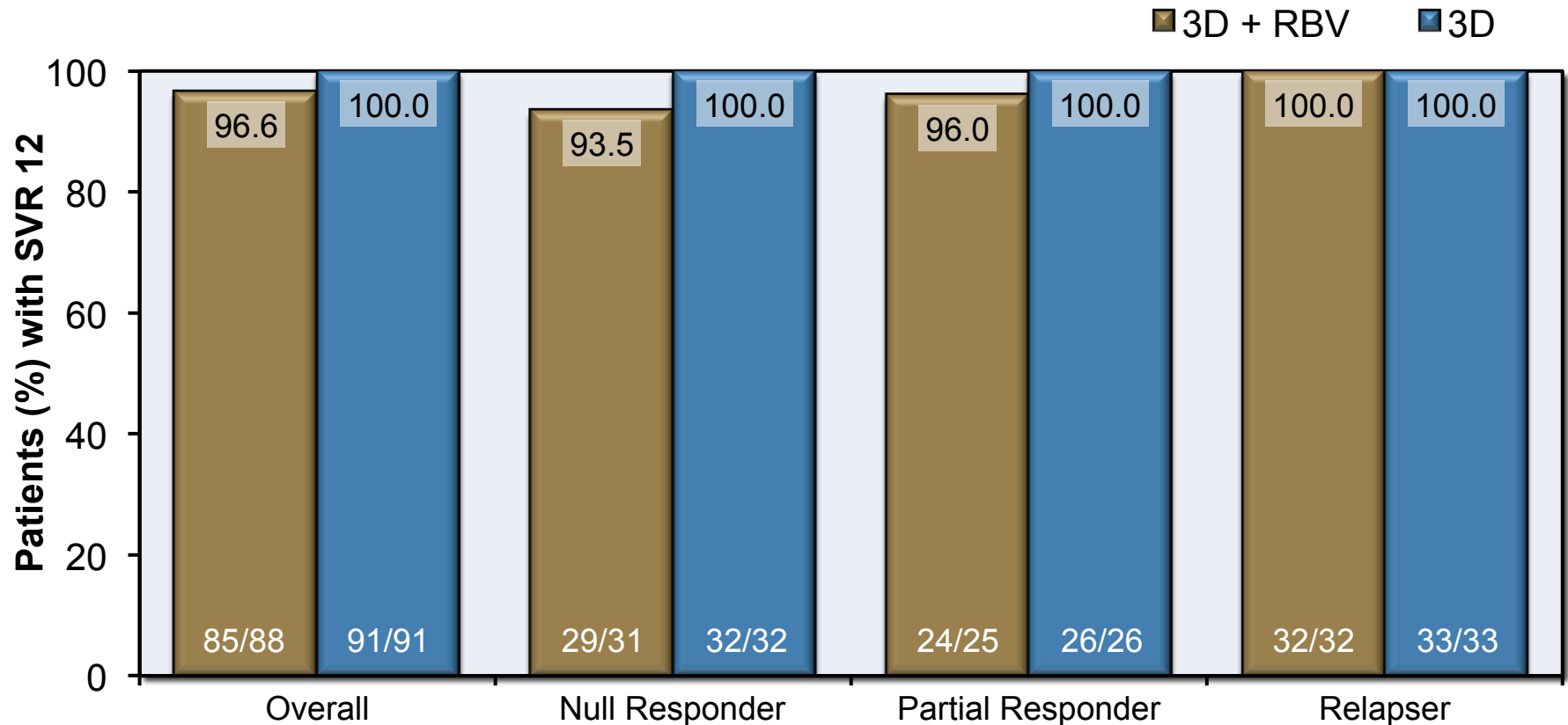
\*Primary endpoint by intention-to-treat analysis

**3D** = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir; **RBV** = ribavirin

Source: Andreone P, et al. *Gastroenterology*. 2014;147:359-65.

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir +/- RBV in GT1b PEARL-II: Results by Prior Treatment Response

## PEARL-II: Results by Prior Treatment Response



3D = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir; RBV = ribavirin

Source: Andreone P, et al. *Gastroenterology*. 2014;147:359-65.

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir +/- RBV in GT1b PEARL-II: Treatment-Emergent Adverse Effects

Event	3D + RBV (n=91)	3D (n=95)
Any Treatment Emergent Adverse Effect %	79.1	77.9
Any serious Treatment Emergent Adverse Effect %	2.2	0
Common Treatment Emergent Adverse Events:		
Fatigue %	31.9	15.8
Headache %	24.2	23.2
Nausea %	20.9	6.3
Insomnia %	14.3	3.2
Pruritus %	14.3	8.4
Diarrhea %	13.2	12.6
Asthenia %	12.1	7.4
Anemia %	11.0	0
Blood bilirubin level increased %	8.8	0
Rash %	8.8	1.1
Laboratory abnormalities (%):		
Hemoglobin (< lower limit of normal at end of treatment)	42.0	5.5
Total bilirubin > 3x ULN	8.8	0

**3D** = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir; **RBV** = Ribavirin

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir +/- RBV in GT1b PEARL-II: Conclusions

**Conclusions:** “The interferon-free regimen of ABT-450, ritonavir, ombitasvir, and dasabuvir, with or without ribavirin, produces a high rate of SVR12 in treatment-experienced patients with HCV genotype 1b infection. Both regimens are well tolerated, as shown by the low rate of discontinuations and generally mild adverse events.”

**Note:** ABT-450 = Paritaprevir

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir in Treatment-Naïve and Treatment-Experienced Patients

# 3D (Ombitasvir-Paritaprevir-Ritonavir + Dasabuvir) + RBV in GT1 TURQUOISE-I

Sulkowski MS, et al. JAMA. 2015;313:1223-31.

# 3D + Ribavirin for HCV-HIV Coinfection and GT1

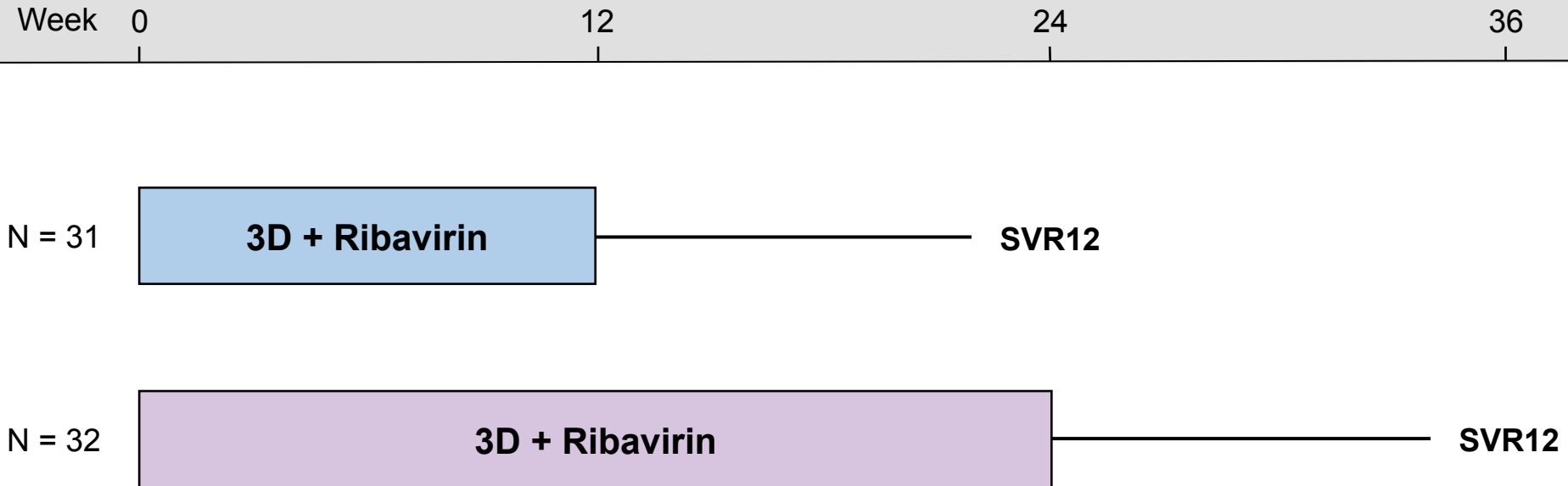
## TURQUOISE-I: Part 1a Study Design

### TURQUOISE-I: Features

- **Design:** Multipart, phase 2/3, randomized, open-label trial evaluating safety and efficacy of 3D (ombitasvir-paritaprevir-ritonavir and dasabuvir) plus ribavirin for 12 or 24 weeks in treatment-naïve and experienced patients with chronic HCV GT 1 and HIV coinfection, including patients with cirrhosis
- **Setting:** Multicenter study in United States and Puerto Rico
- **Entry Criteria**
  - Chronic HCV infection with genotype 1 and HIV coinfection
  - Treatment-naïve or previously treated with peginterferon + ribavirin
  - Age 18-70
  - Plasma HCV RNA greater than 10,000 IU/mL
  - Child-Pugh A cirrhosis permitted
  - CD4 count  $\geq 200$  cells/mm<sup>3</sup> (or CD4%  $\geq 14$ ) and HIV RNA level  $< 40$  copies/ml
  - Receiving atazanavir- or raltegravir-based regimen
- **Primary End-Point:** SVR12

# 3D + Ribavirin for HCV-HIV Coinfection and GT1

## TURQUOISE-I: Part 1a Study Regimens



**3D** = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir

### Drug Dosing

Ombitasvir-Paritaprevir-Ritonavir (25/150/100 mg once daily) and Dasabuvir: 250 mg twice daily

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



# 3D + Ribavirin for HCV-HIV Coinfection and GT 1

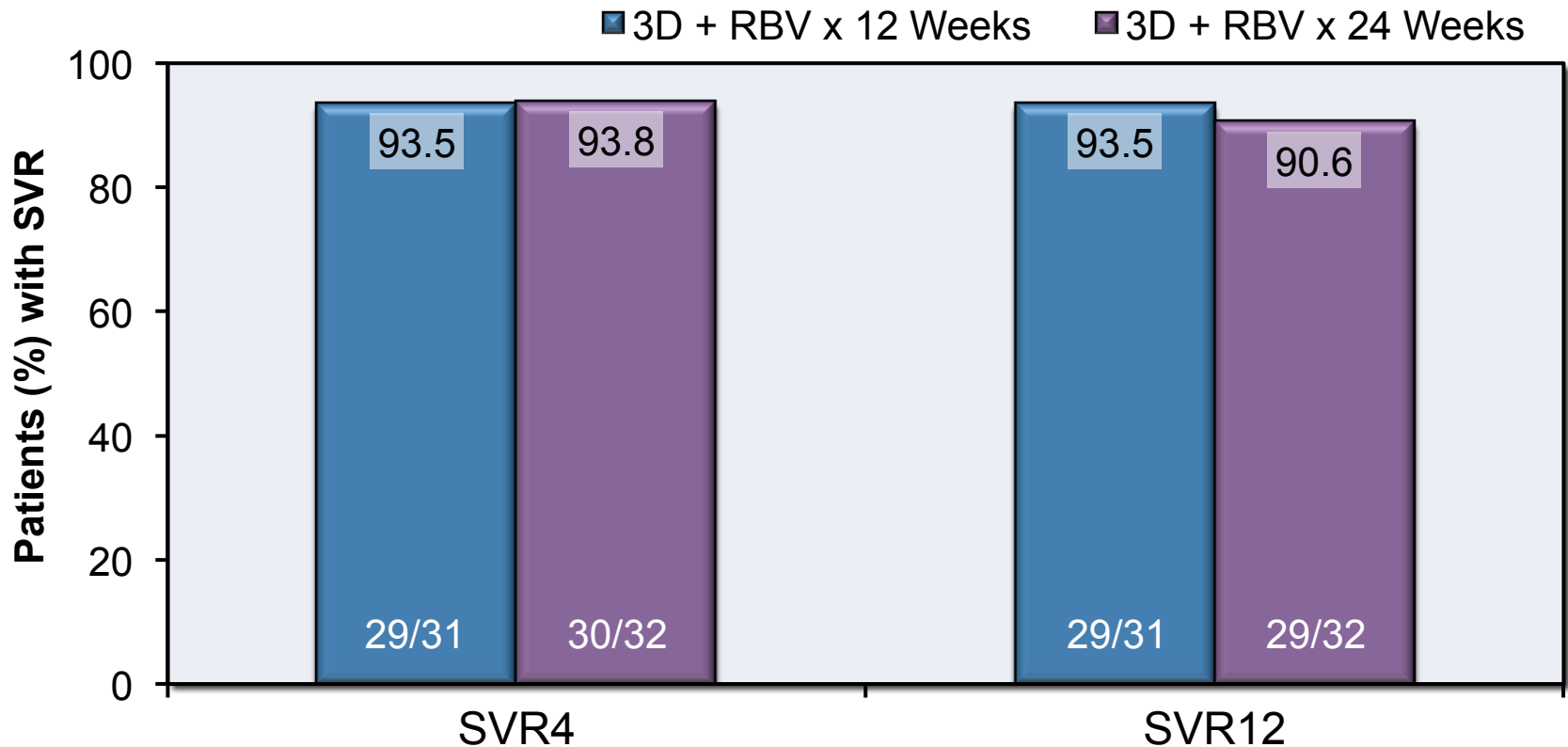
## TURQUOISE-I: Patient Population

Baseline Characteristic	12-Week Arm (n=31)	24-Week Arm (n=32)
Age (years), Mean	50.9	50.9
Male sex %	94	91
Black Race (%)	23	25
Cirrhosis (%)	19	19
HCV genotype (%)		
1a	87	91
1b	13	9
HCV RNA, log <sub>10</sub> IU/ml (mean)	6.54	6.60
IL28B non-CC genotype, (%)	84	78
Previous Response to PEG + RBV		
Naïve	65	69
Relapse	3	9
Partial response	16	6
Null response	16	16
CD4 Count, cells/mm <sup>3</sup> (mean)	633	625

Source: Sulkowski MS, et al. JAMA. 2015;313:1223-31.

# 3D + Ribavirin for HCV-HIV Coinfection and GT 1 TURQUOISE-I: Part 1a Results

TURQUOISE-I: SVR Rates (to date)



**3D** = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir; **RBV** = Ribavirin

Source: Sulkowski MS, et al. JAMA. 2015;313:1223-31.

# 3D + Ribavirin for HCV-HIV Coinfection and GT 1 TURQUOISE-I: Part 1a Results

## Details of Five Patients NOT Achieving SVR 12

- One patient in 12-week arm withdrew consent prior to finishing treatment; had undetectable HCV RNA at week 10
- One patient in 12-week arm had virologic relapse at week 4 post treatment; had new resistant HCV variants at 3 viral targets (D168V in NS3/4A, M28T in NS5A, and S556G in NS5B)
- One patient in 24-week arm had virologic breakthrough during treatment; had new resistant HCV variants at 3 viral targets (R155K in NS3/4A, Q30R in NS5A, and S556G in NS5B)
- Two patients in 24-week arm achieved early SVR but appeared to be reinfected with GT1a isolate distinct from baseline HCV isolate; both patients had engaged in high-risk sexual activity post treatment

# 3D + Ribavirin for HCV-HIV Coinfection and GT 1

## TURQUOISE-I: Part 1a Conclusions and Relevance

**Conclusions and Relevance:** “In this open-label, randomized uncontrolled study, treatment with the all-oral, interferon-free 3D-plus-ribavirin regimen resulted in high SVR rates among patients co-infected with HCV genotype 1 and HIV-1 whether treated for 12 or 24 weeks. Further phase 3 studies of this regimen are warranted in patients with co-infection.”

Treatment Naïve and Treatment Experienced

Compensated Cirrhosis

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + RBV in GT1 TURQUOISE-II

Poordad F, et al. N Engl J Med. 2014;370:1973-82.

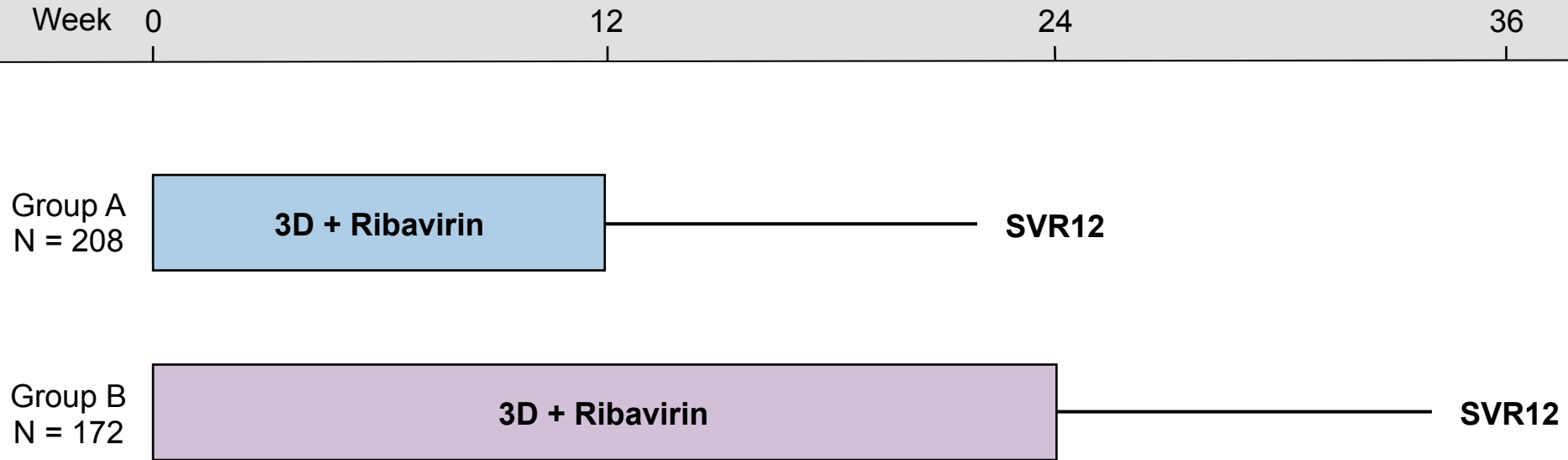
# 3D + Ribavirin in GT1 and Compensated Cirrhosis

## TURQUOISE-II: Study Design

### TURQUOISE-II: Features

- **Design:** Phase 3, randomized, open-label trial evaluating safety and efficacy of 3D (ombitasvir-paritaprevir-ritonavir & dasabuvir) + ribavirin for 12 or 24 weeks in treatment-naïve and experienced patients with chronic HCV GT 1 and compensated cirrhosis
- **Setting:** 78 sites in North America and Europe
- **Entry Criteria**
  - Chronic HCV infection with genotype 1
  - Treatment-naïve or previously treated with peginterferon + RBV
  - Age 18-70
  - Plasma HCV RNA greater than 10,000 IU/mL
  - Cirrhosis (Metavir >3, Ishak score >4 or Fibroscan  $\geq 14.6$  kPa)
  - Cirrhosis is compensated (Child-Pugh score <7 at screening)
  - Absence of coinfection with HBV or HIV
- **Primary End-Point:** SVR12

# 3D + Ribavirin in GT1 and Compensated Cirrhosis TURQUOISE-II: Regimens



**3D** = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir

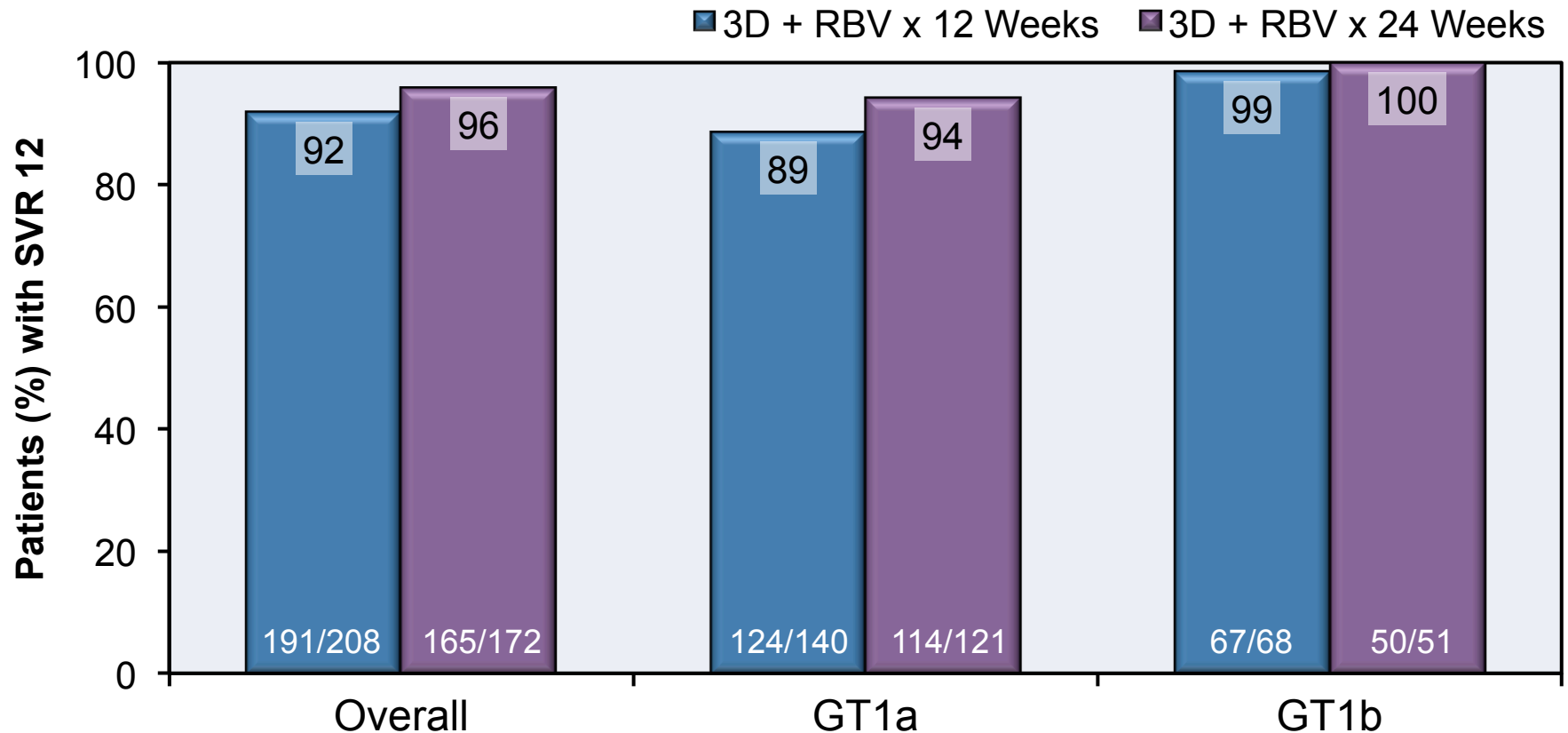
## Drug Dosing

Ombitasvir-Paritaprevir-Ritonavir (25/150/100 mg once daily) + Dasabuvir: 250 mg twice daily

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

# 3D + Ribavirin in GT1 and Compensated Cirrhosis TURQUOISE-II: Results

## TURQUOISE II: SVR12 by Genotype 1 Subtype



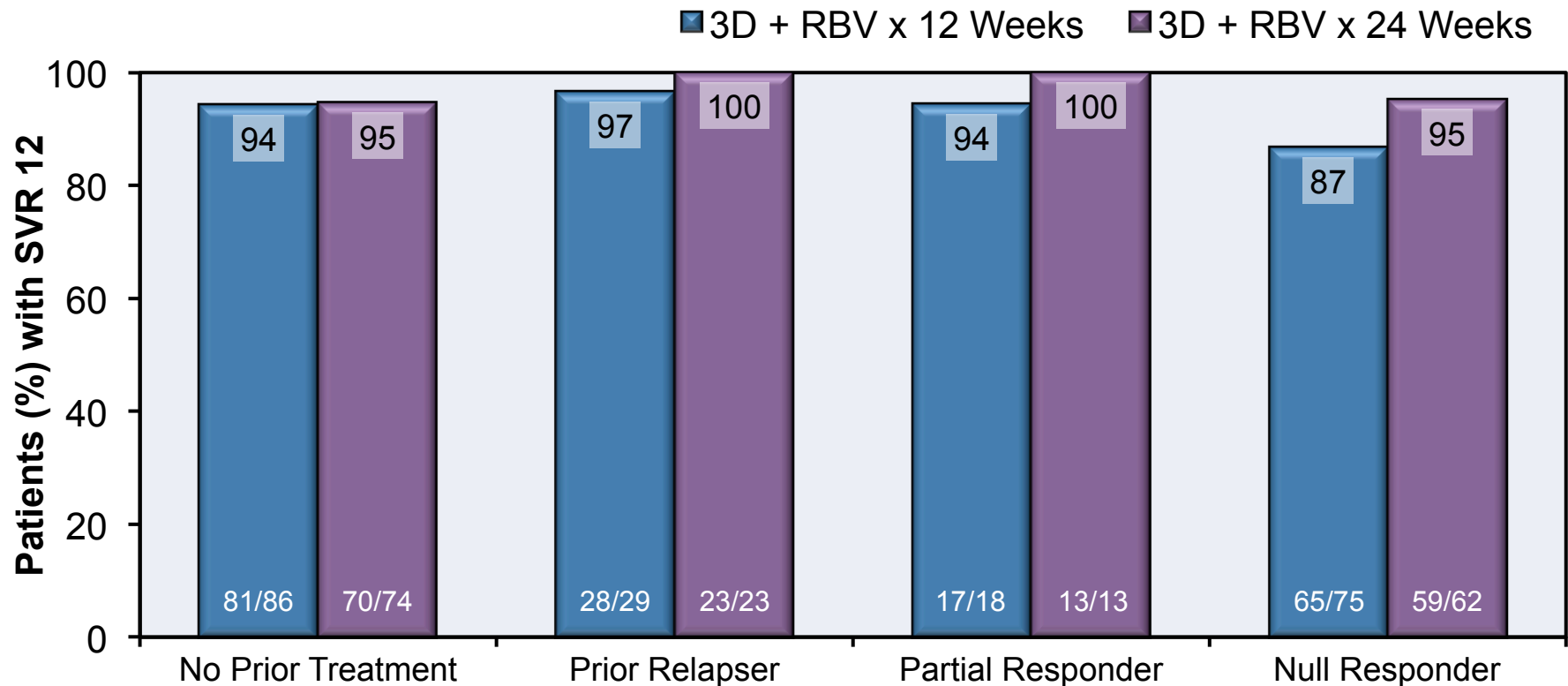
3D = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir; RBV = ribavirin

Source: Poordad F, et al. *N Engl J Med.* 2014;370:1973-82.



# 3D + Ribavirin in GT1 and Compensated Cirrhosis TURQUOISE-II: Results

## TURQUOISE II: SVR12 Based on Prior Treatment

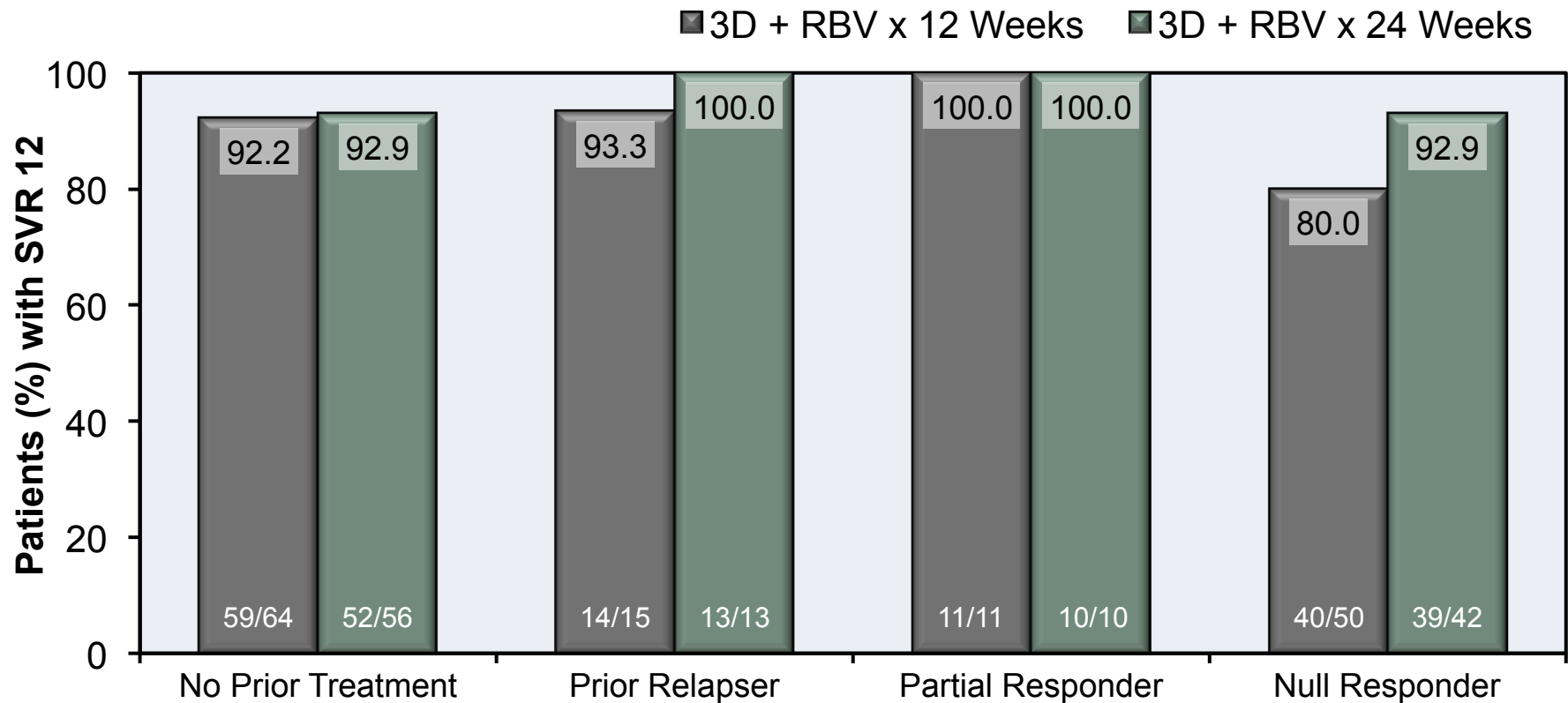


3D = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir; RBV = ribavirin

Source: Poordad F, et al. N Engl J Med. 2014;370:1973-82.

# 3D + Ribavirin in GT1 and Compensated Cirrhosis TURQUOISE-II: Results for GT1a

## TURQUOISE II: Genotype 1a SVR12 Based on Prior Treatment

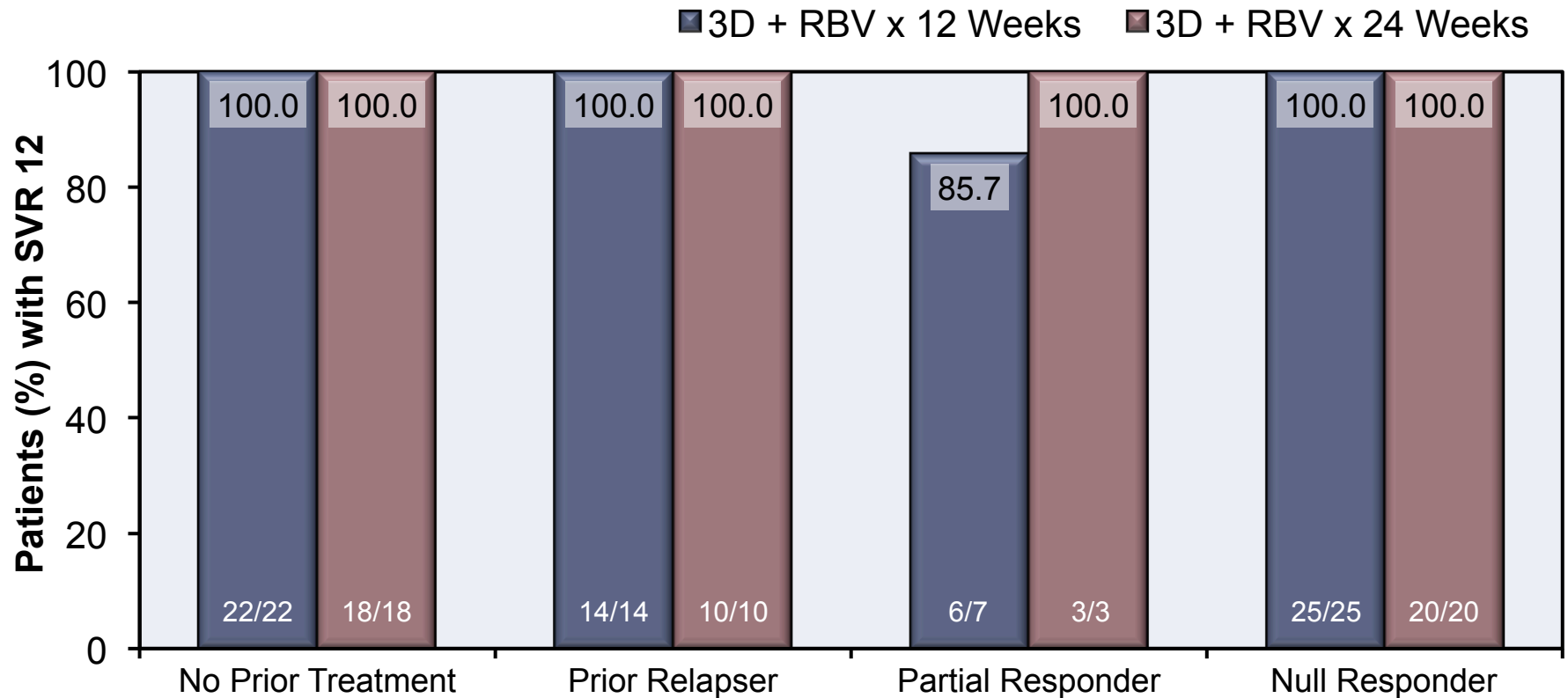


3D = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir; RBV = ribavirin

Source: Poordad F, et al. *N Engl J Med.* 2014;370:1973-82.

# 3D + Ribavirin in GT1 and Compensated Cirrhosis TURQUOISE-II: Results for GT1b

## TURQUOISE II: Genotype 1b SVR12 Based on Prior Treatment



3D = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir; RBV = ribavirin

Source: Poordad F, et al. *N Engl J Med.* 2014;370:1973-82.

# 3D + Ribavirin in GT1 and Compensated Cirrhosis

## TURQUOISE-II: Adverse Effects

Event	3D + RBV x 12 weeks (n=208)	3D + RBV x 24 weeks (n=172)
Any adverse event (%)	91.8	90.7
Adverse event leading to stopping study drug (%)	1.9	2.3
Any serious adverse event	6.2	4.7
Most common adverse event		
Fatigue (%)	32.7	46.5
Headache (%)	27.9	30.8
Nausea (%)	17.8	20.3
Pruritis (%)	18.3	19.2
Insomnia (%)	15.4	18.0
Diarrhea (%)	14.4	16.9
Asthenia (%)	13.9	12.8
Rash (%)	11.1	14.5
Irritability (%)	7.2	12.2
Anemia (%)	7.7	10.5
Dyspnea (%)	5.8	12.2

**3D** = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir; **RBV** = ribavirin

Source: Poordad F, et al. *N Engl J Med.* 2014;370:1973-82.

# 3D + Ribavirin in GT1 and Compensated Cirrhosis

## TURQUOISE-II: Adverse Effects

Lab Abnormalities	3D + RBV x 12 weeks (n=208)	3D + RBV x 24 weeks (n=172)
Alanine aminotransferase, grade 3 or 4	6 (2.9)	0
Aspartate aminotransferase, grade 3 or 4	1 (0.5)	0
Alkaline phosphatase, grade 3 or 4	0	0
Total bilirubin, grade 3 or 4	28 (13.5)	9 (5.2)
Hemoglobin		
Grade 1	103 (49.5)	97 (56.4)
Grade 2	12 (5.8)	18 (10.5)
Grade 3	2 (1.0)	1 (0.6)
Grade 4	1 (0.5)	0

**3D** = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir; **RBV** = ribavirin

# 3D + Ribavirin in GT1 and Compensated Cirrhosis

## TURQUOISE-II: Conclusions

**Conclusions:** “In this phase 3 trial of an oral, interferon-free regimen evaluated exclusively in patients with HCV genotype 1 infection and cirrhosis, multitargeted therapy with the use of three new antiviral agents and ribavirin resulted in high rates of sustained virologic response. Drug discontinuations due to adverse events were infrequent.”

Treatment Naïve and Treatment Experienced

Compensated Cirrhosis

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir in GT1b TURQUOISE-III

Feld JJ, et al. J Hepatol. 2016;64:301-7.

# OMB-PTV-RTV + DSV in GT1b and Compensated Cirrhosis

## TURQUOISE-III: Study Design

### TURQUOISE-III: Features

- **Design:** Phase 3, open-label trial evaluating safety and efficacy of ombitasvir-paritaprevir-ritonavir and dasabuvir given for 12 weeks in treatment-naïve and treatment-experienced adults with chronic HCV GT 1b and compensated cirrhosis
- **Setting:** 19 sites in United States, Canada, and Belgium
- **Entry Criteria**
  - Chronic HCV infection with genotype 1b
  - Treatment-naïve or previously treated with peginterferon + ribavirin
  - Age  $\geq 18$  years
  - Plasma HCV RNA greater than 1,000 IU/mL
  - Documented cirrhosis (Metavir  $>3$ , Ishak score  $>4$  or Fibroscan  $\geq 12.5$  kPa)
  - Cirrhosis is compensated (Child-Pugh score  $<7$  at screening)
  - Absence of coinfection with HBV or HIV
- **Primary End-Point:** SVR12



# OMB-PTV-RTV + DSV in GT1b and Compensated Cirrhosis TURQUOISE-III: Study Design

Week 0 12 24

GT1b  
n = 60

Ombitasvir-Paritaprevir-Ritonavir  
and Dasabuvir

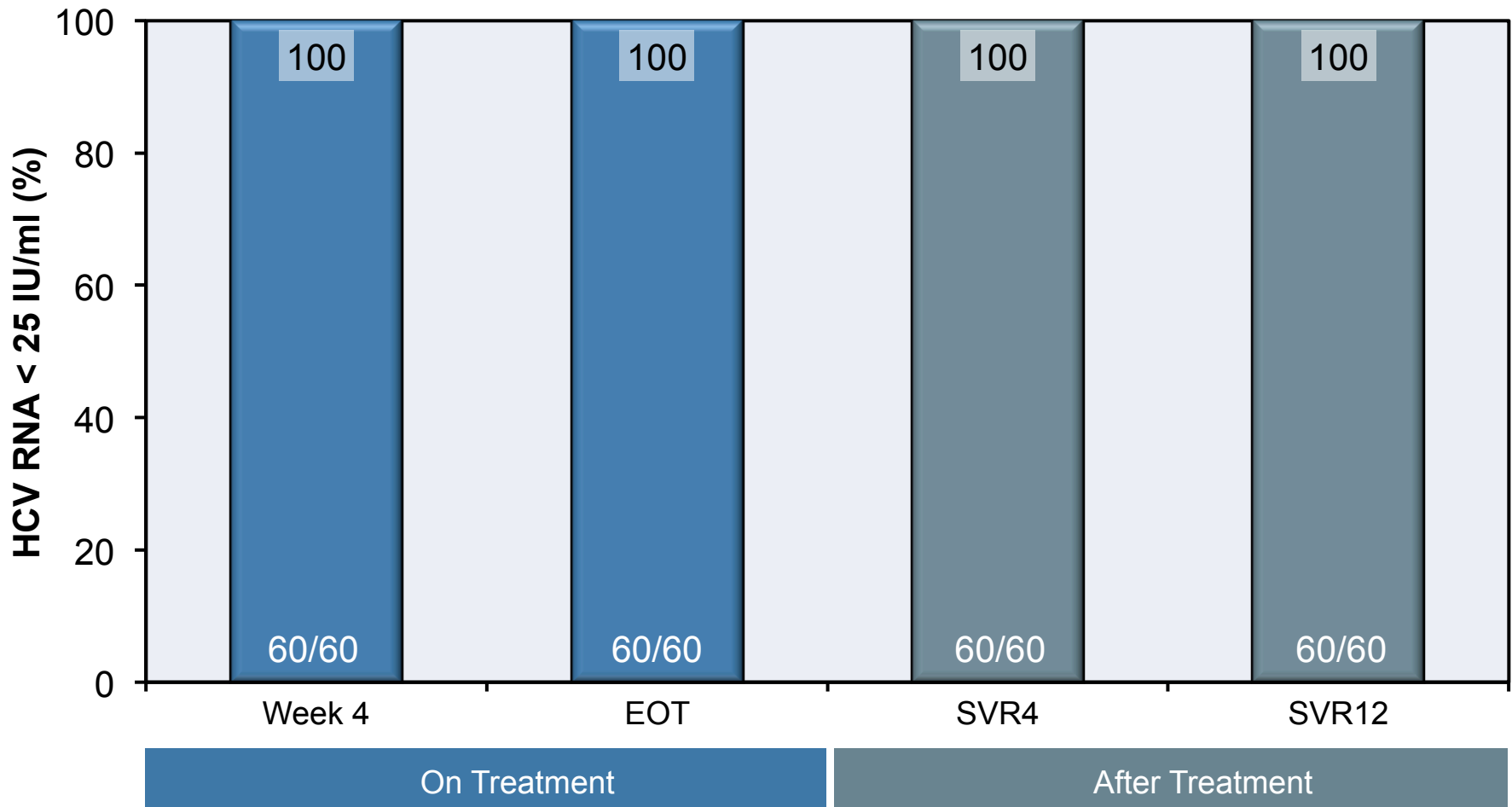
SVR12

## Drug Dosing

Ombitasvir-Paritaprevir-Ritonavir (25/150/100 mg once daily) + Dasabuvir: 250 mg twice daily

# OMB-PTV-RTV + DSV in GT1b and Compensated Cirrhosis TURQUOISE-III: Results

Virologic Response to Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir



Source: Feld JJ, et al. J Hepatol. 2016;64:301-7.

# OMB-PTV-RTV + DSV in GT1b and Compensated Cirrhosis TURQUOISE-III: Adverse Effects

Common Adverse Events (≥10% of patients)	OMB-PTV-RTV + DSV x 12 weeks (n = 60)
Fatigue (%)	13 (21.7)
Diarrhea (%)	12 (20.0)
Headache (%)	11 (18.3)
Arthralgia (%)	6 (10.0)
Dizziness (%)	6 (10.0)
Insomnia (%)	6 (10.0)
Pruritis (%)	6 (10.0)
<b>Abbreviations:</b> OMB= Ombitasvir; PTV = Paritaprevir; RTV = Ritonavir; DSV= Dasabuvir	

# OMB-PTV-RTV + DSV in GT1b and Compensated Cirrhosis TURQUOISE-III: Adverse Effects

Laboratory Abnormalities	OMB-PTV-RTV + DSV x 12 weeks (n = 60)
Hemoglobin(%)	13 (21.7)
Total bilirubin	
Grade 2 (>1.5-3 x ULN)	12 (20.0)
Grade 3 (>3-10 x ULN)	0
Alanine aminotransferase (%)	
Grade 3 (>5-20 x ULN)	1 (1.7)
Aspartate aminotransferase (%)	
Grade 3 (>5-20 x ULN)	0
<b>Abbreviations:</b> OMB= Ombitasvir; PTV = Paritaprevir; RTV = Ritonavir; DSV= Dasabuvir	

# OMB-PTV-RTV + DSV in GT1b and Compensated Cirrhosis TURQUOISE-III: Conclusions

**Conclusions:** “The HCV regimen of ombitasvir/paritaprevir/ritonavir and dasabuvir without ribavirin for 12 weeks achieved 100% SVR12 and was well tolerated in HCV genotype 1b-infected patients with cirrhosis, suggesting that this 12-week ribavirin-free regimen is sufficient in this population.”

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir in Patients with HCV-HIV Coinfection

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir in Patients Pre and Post Liver Transplant

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + RBV in Liver Transplant Recipients with Recurrent HCV GT1

## CORAL-I

Kwo PY, et al. N Engl J Med. 2014;371:2375-82.



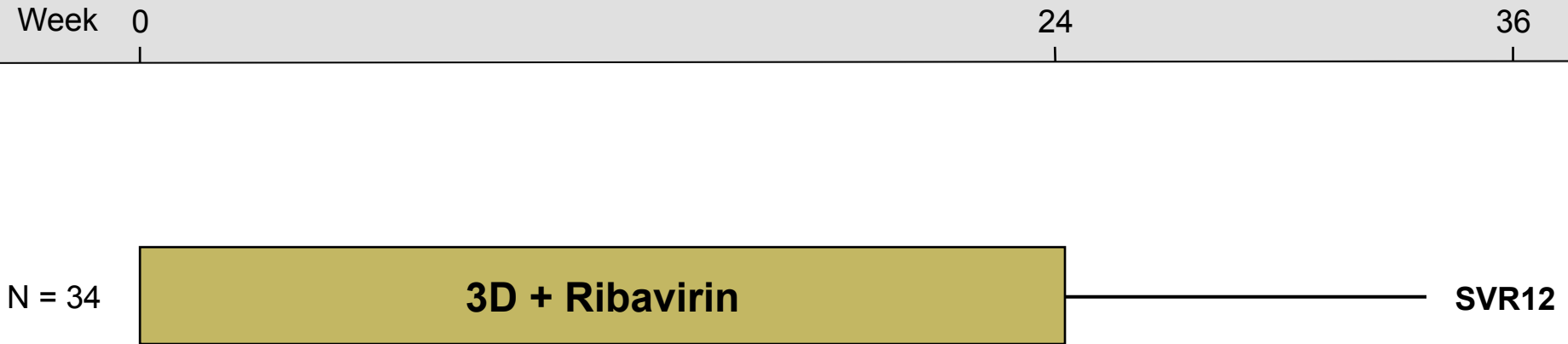
# 3D + RBV in Liver Transplant Recipients with Recurrent HCV GT1

## CORAL-I Trial: Study Design

### CORAL-I: Features

- **Design:** Phase 2, open-label, single-arm trial evaluating safety and efficacy of 3D (ombitasvir-paritaprevir-ritonavir + dasabuvir) + ribavirin x 24 weeks in liver transplant recipients with recurrent HCV GT 1
- **Setting:** International
- **Entry Criteria**
  - Chronic HCV infection with genotype 1
  - Liver transplantation due to HCV at least 12 months prior
  - Treatment-naïve after transplantation
  - Pre-transplant treatment with peginterferon + ribavirin allowed
  - Age 18-70
  - Metavir score  $\leq$ F2 confirmed by liver biopsy
- **Use of Immunosuppressants**
  - Receiving stable immunosuppressant regimen (tacrolimus or cyclosporin)
  - Tacrolimus or cyclosporin dose based on phase I pharmacokinetic study
  - Prednisone at dose  $\leq$  5 mg/day permitted but not use of mTOR inhibitors
- **Primary End-Point:** SVR12

# 3D + RBV in Liver Transplant Recipients with Recurrent HCV GT1 CORAL-I Trial: Regimen



**3D** = Ombitasvir-Paritaprevir-Ritonavir + Dasabuvir

## Drug Dosing

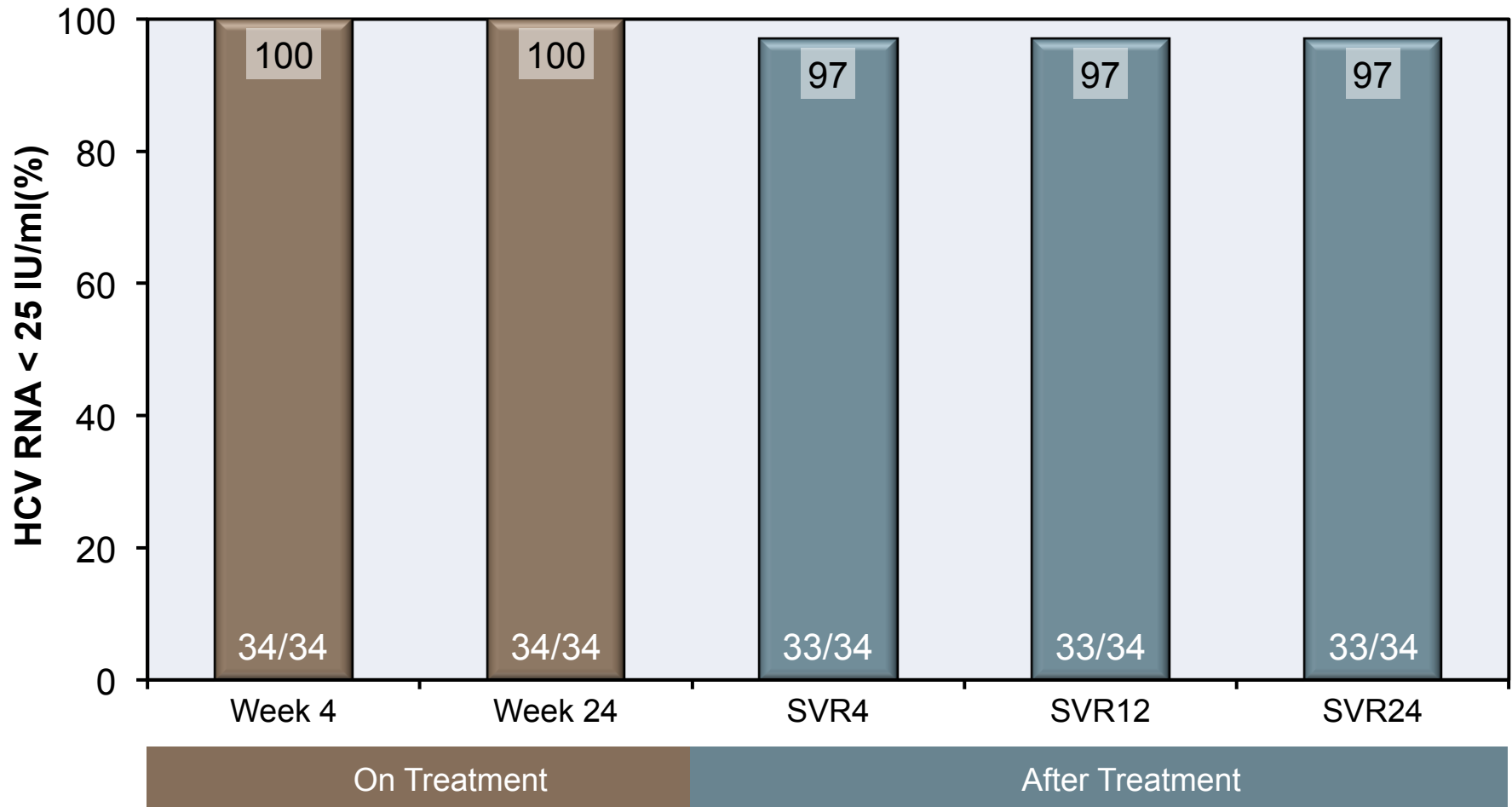
Ombitasvir-Paritaprevir-Ritonavir- (25/150/100 mg once daily) + Dasabuvir: 250 mg twice daily

Ribavirin (RBV): dosing managed per investigator discretion; most patients received 600-800 mg/day

# 3D + RBV in Liver Transplant Recipients with Recurrent HCV GT1 CORAL-I Trial: Baseline Characteristics

Baseline Characteristic	3D + Ribavirin (n=34)
Age (years), Mean	59.6
Male sex—no. (%)	27 (79)
Race—no. (%)	
White	29 (85)
Black	4 (12)
Multiple	1 (3)
Body Mass Index (kg/m <sup>2</sup> ) Mean	29.7
HCV genotype—no. (%)	
1a	29 (85)
1b	5 (15)
IL28B, non-CC genotype—no. (%)	26 (76)
HCV RNA, log <sub>10</sub> IU/ml	6.6
Fibrosis stage (%)	
F0	6 (18)
F1	13 (38)
F2	15 (44)
<b>3D</b> = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir; <b>RBV</b> = ribavirin	

# 3D + RBV in Liver Transplant Recipients with Recurrent HCV GT1 CORAL-I Trial: Results



Source: Kwo PY, et al. N Engl J Med. 2014;371:2375-82.

# 3D + RBV in Liver Transplant Recipients with Recurrent HCV GT1 CORAL-I Trial: Adverse Events

Adverse Event Occurring in > 15% of the 34 Patients Receiving 3D + RBV	
Event	N (%)
Any adverse event	33 (97)
Fatigue	17 (50)
Headache	15 (44)
Cough	11 (32)
Anemia	10 (29)
Diarrhea	9 (26)
Insomnia	9 (26)
Asthenia	8 (24)
Nausea	8 (24)
Muscle spasms	7 (21)
Rash	7 (21)
Back pain	6 (18)
Dizziness	6 (18)
Peripheral edema	6 (18)
Rhinorrhea	6 (18)

**3D** = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir; **RBV** = ribavirin

# 3D + RBV in Liver Transplant Recipients with Recurrent HCV GT1 CORAL-I Trial: Conclusions

**Conclusions:** “Treatment with the multitargeted regimen of ombitasvir-ABT-450/r and dasabuvir with ribavirin was associated with a low rate of serious adverse events and a high rate of sustained virologic response among liver-transplant recipients with recurrent HCV genotype 1 infection, a historically difficult-to-treat population.”

**Note:** ABT-450/r = Paritaprevir-Ritonavir

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir in Patients with Renal Disease

Treatment-Naive

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir in GT1 and Renal Disease RUBY-I

Pockros PJ, Gastroenterology. 2016;150:1590-8.



# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir in GT1 & Renal Disease

## RUBY-I: Study Design

### RUBY-I: Features

- **Design:** Phase 3b, randomized, open-label trial evaluating safety and efficacy of 3D (ombitasvir-paritaprevir-ritonavir and dasabuvir) with or without ribavirin for 12 weeks in treatment-naïve patients with chronic HCV GT1 and advanced kidney disease
- **Setting:** 9 sites in United States
- **Entry Criteria**
  - Adults with chronic HCV genotype 1 infection
  - Chronic kidney disease stage 4 or 5 (eGFR <30 mL/min/1.73 m<sup>2</sup>) +/- HD
  - Plasma HCV RNA greater than 1,000 IU/mL
  - Absence of cirrhosis
  - Absence of coinfection with HBV or HIV
  - Baseline Hb ≥10 g/dL
- **Primary End-Point:** SVR12

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir in GT1 & Renal Disease

## RUBY-I: Regimens

Week 0

12

24

GT 1a  
n = 13

**Ombitasvir-Paritaprevir-Ritonavir  
and Dasabuvir + Ribavirin**

SVR12

GT 1b  
n = 7

**Ombitasvir-Paritaprevir-Ritonavir  
and Dasabuvir**

SVR12

### Drug Dosing

Ombitasvir-Paritaprevir-Ritonavir (25/150/100 mg once daily) + Dasabuvir: 250 mg twice daily

Ribavirin for patients not on hemodialysis: 200 mg once daily

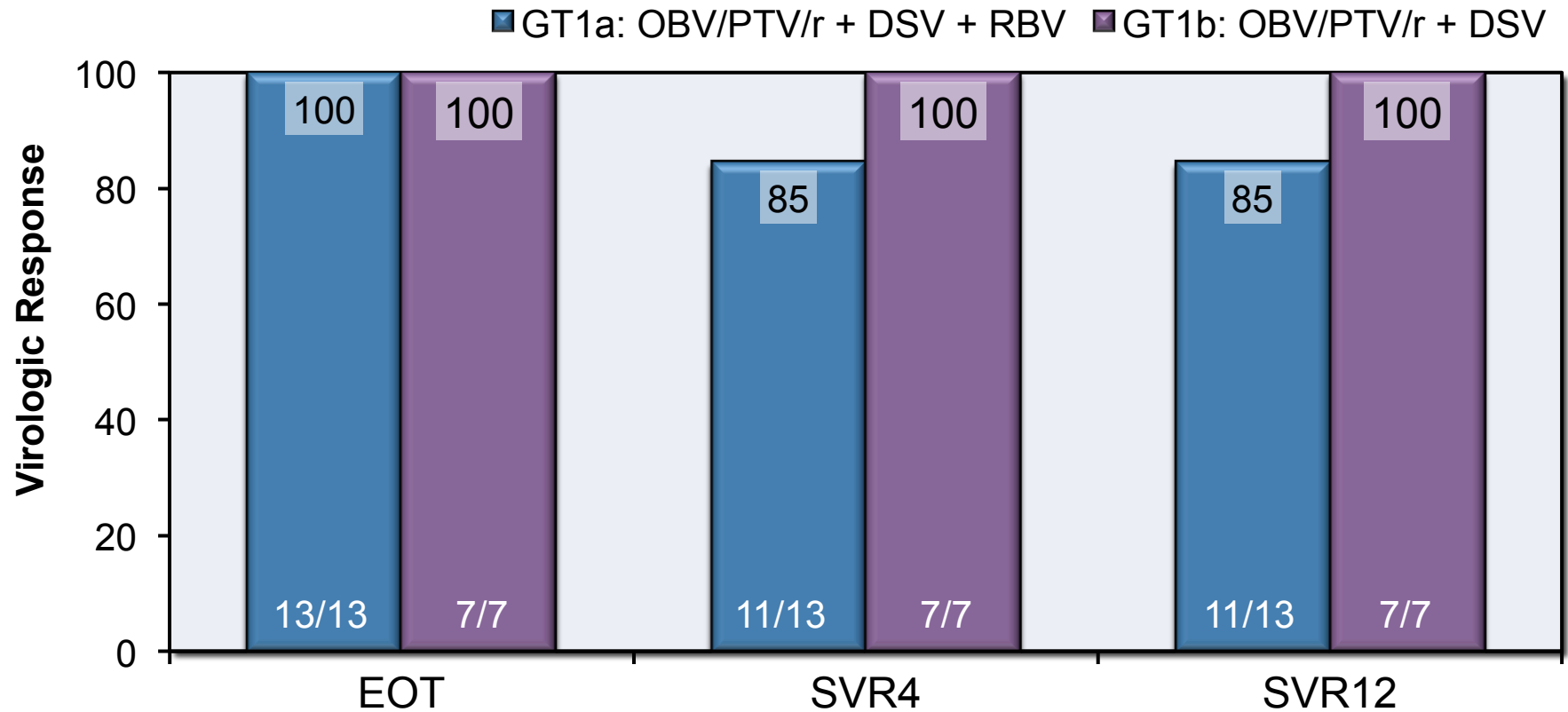
Ribavirin for patients on hemodialysis: 200 mg given 4 hours before each hemodialysis session

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir in GT1 & Renal Disease RUBY-I: Baseline Characteristics

Baseline Characteristic	All Patients (n = 20)
Male, %	17 (85%)
Median age, years (range)	60 (49-69)
Race	
Black	14 (70%)
Hispanic	3 (15%)
Median HCV RNA, log <sub>10</sub> IU/ml (range)	6.6 (5.5-7.6)
Degree of Fibrosis, n (%)	
F0-F1	10 (50%)
F2	6 (30%)
F3	4 (20%)
CKD Stage; n (%)	
4 (eGFR 15-30 mL/min/1.73 m <sup>2</sup> )	6 (30)
5 (eGFR <15 mL/min/1.73 m <sup>2</sup> or requiring HD)	14 (70)
eGFR, mL/min/1.73 m <sup>2</sup>	10.9 (5.4-29.9)

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir in GT1 & Renal Disease RUBY-I: Baseline Results

RUBY-I: SVR 12 Rates\*



OBV/PTV/r + DSV = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir; RBV = ribavirin

Source: Pockros PJ, Gastroenterology. 2016;150:1590-8.

# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir in GT1 & Renal Disease

## RUBY-I: Conclusions

**Conclusions:** “In a clinical trial, the combination of ombitasvir, paritaprevir, and ritonavir, administered with dasabuvir, led to an SVR12 in 90% of patients with HCV genotype 1 infection and stage 4 or 5 CKD. The regimen is well tolerated, though ribavirin use may require a reduction or interruption to manage anemia.”

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/>

Funded by a grant from the Centers for Disease Control and Prevention.