

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

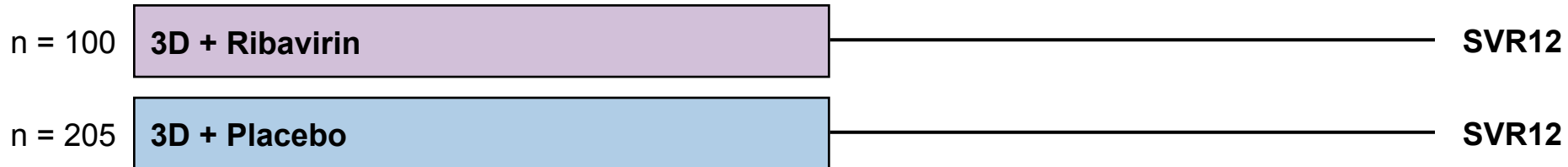
## PEARL-III and PEARL-IV: Features

- **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

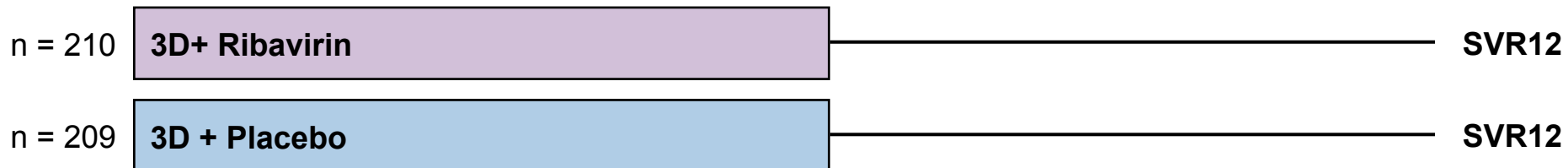
# Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir +/- RBV in GT1 PEARL-III and PEARL-IV: Study Regimens

Week 0 | 12 | 24

## HCV Genotype 1a



## HCV Genotype 1b



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

### Drug Dosing

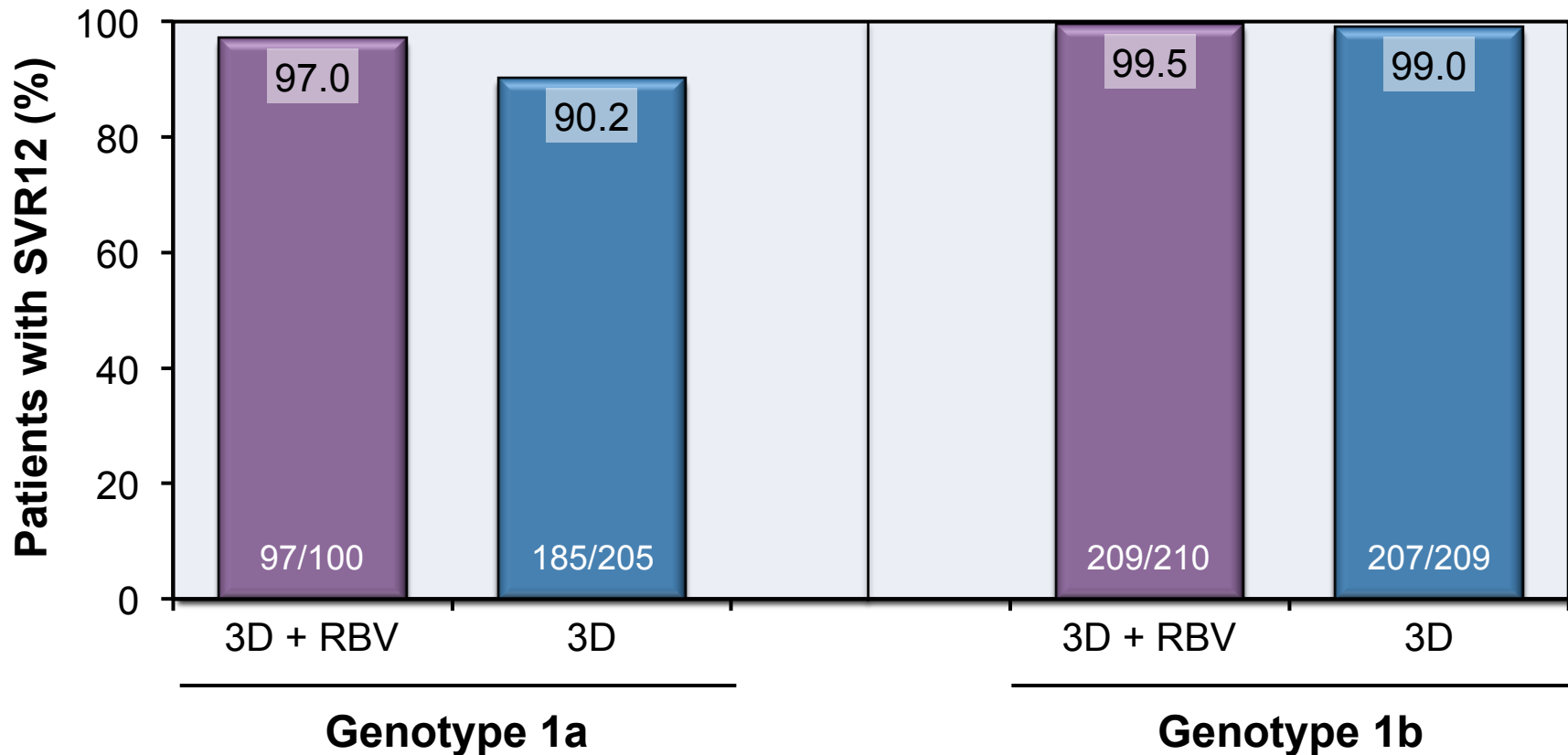
3D = Ombitasvir-Paritaprevir-Ritonavir (25/150/100 mg once daily) + Dasabuvir: 250 mg twice daily  
 Ribavirin (RBV): weight-based and divided bid (1000 mg/day if < 75kg or 1200 mg/day if ≥ 75kg)

# 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

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

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



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

# 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

# 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

# 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



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.