

Treatment Naïve and Treatment Experienced

Ombitasvir + Paritaprevir + Ritonavir +/- Ribavirin in HCV GT4 PEARL-I

Hézode C, et al. Lancet. 2015 March 30. [Epub ahead of print]

Ombitasvir + Paritaprevir + Ritonavir +/- RBV in HCV GT4

PEARL-I: Study Design

PEARL-I: Features

- **Design:** Phase 2b, 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 and treatment-experienced patients with chronic HCV GT 4
- **Setting:** multicenter at international sites
- **Entry Criteria**
 - Chronic HCV infection with genotype 4
 - Treatment naïve or prior treatment 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 +/- RBV in HCV GT4 PEARL-I: Regimens

Week 0

12

24

HCV Treatment Naïve GT4

n = 44

**Ombitasvir + Paritaprevir +
Ritonavir**

SVR12

n = 42

**Ombitasvir + Paritaprevir +
Ritonavir + Ribavirin**

SVR12

HCV Treatment Experienced GT4

n = 49

**Ombitasvir + Paritaprevir +
Ritonavir + Ribavirin**

SVR12

Drug Dosing

Ombitasvir (25 mg once daily), Paritaprevir (150 mg once daily), Ritonavir (100 mg once daily)

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

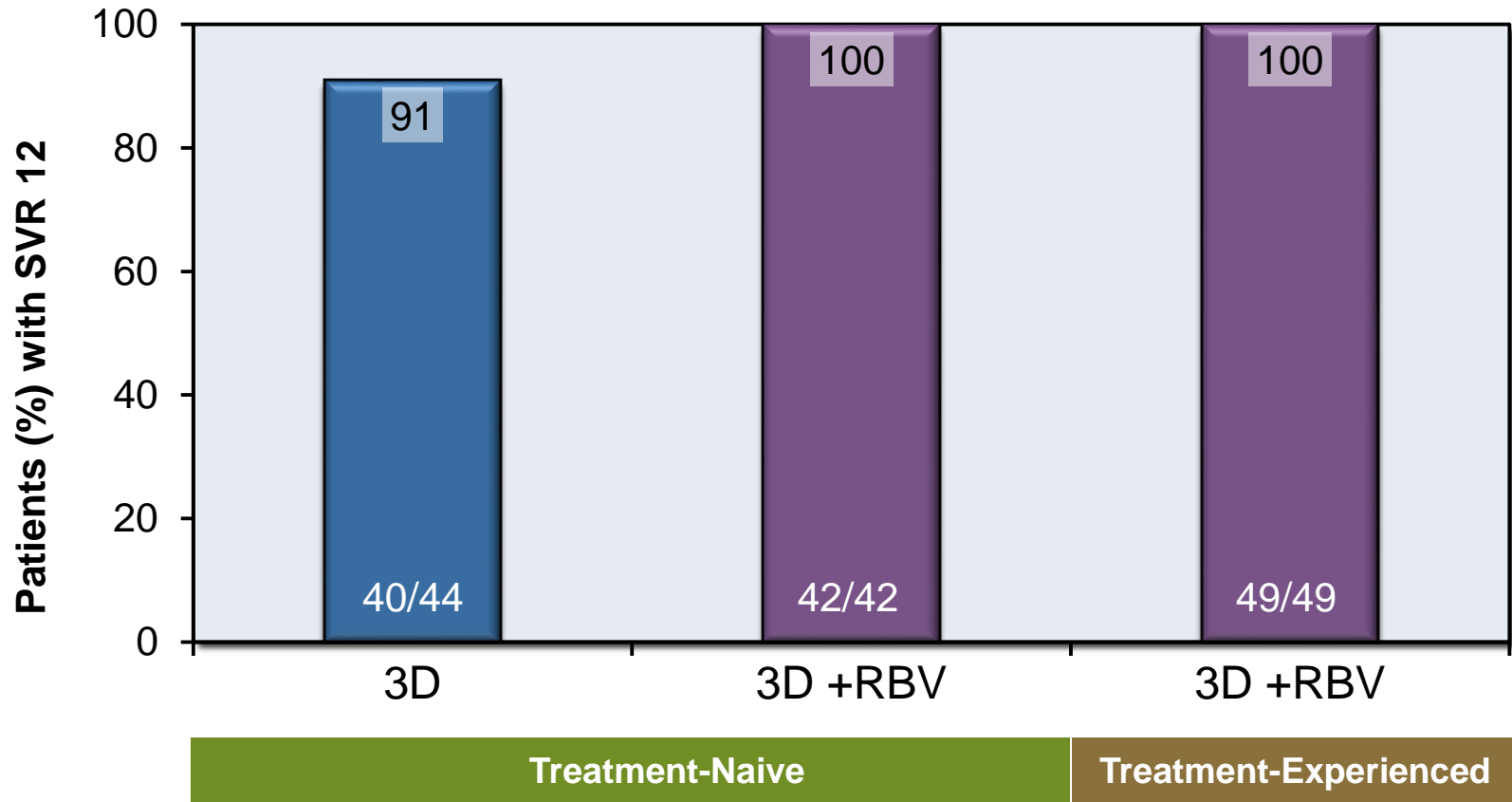
Ombitasvir + Paritaprevir + Ritonavir +/- RBV in HCV GT4 PEARL-I: Baseline Characteristics

Baseline Characteristic	Treatment Naive		Treatment Experienced
	3D (n=44)	3D + RBV (n=42)	3D + RBV (n=49)
Age, years	49	44	51
BMI kg/m ²	25	25	27
IL28B			
CC	27%	26%	12%
CT	55%	62%	65%
TT	18%	12%	22%
HCV RNA log ₁₀ IU/ml	6.1	6.1	6.3
HCV RNA ≥ 800,000 IU/ml	61%	71%	76%
Fibrosis Stage			
F0-F1	86%	79%	67%
F2	9%	14%	22%
F3	15%	7%	10%

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

Ombitasvir + Paritaprevir + Ritonavir +/- RBV in HCV GT4 PEARL-I: Results

PEARL-I: SVR 12 Rates*



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

Ombitasvir + Paritaprevir + Ritonavir +/- RBV in HCV GT4 PEARL-I: Adverse Events

Baseline Characteristic	Treatment Naive		Treatment Experienced
	3D (n=44)	3D + RBV (n=42)	3D + RBV (n=49)
Any adverse event	34 (77%)	37 (88%)	43 (88%)
Any serious adverse event	1 (2%)	0	0
Adverse event leading to drug D/C	0	0	0
Asthenia	11 (25%)	10 (24%)	16 (33%)
Diarrhea	2 (5%)	6 (14%)	3 (6%)
Fatigue	3 (7%)	5 (12%)	9 (18%)
Headache	13 (30%)	14 (33%)	14 (29%)
Insomnia	2 (5%)	4 (10%)	8 (16%)
Irritability	3 (7%)	6 (14%)	2 (4%)
Myalgias	0	0	5 (10%)
Nasopharyngitis	2 (5%)	2 (5%)	6 (12%)
Nausea	4 (9%)	7 (17%)	6 (12%)
Pruritis	2 (5%)	1 (2%)	5 (10%)

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

Ombitasvir + Paritaprevir + Ritonavir +/- RBV in HCV GT4 PEARL-I: Interpretation

Interpretation: “An interferon-free regimen of ombitasvir plus paritaprevir plus ritonavir with or without ribavirin achieved high sustained virological response rates at 12 weeks after the end of treatment and was generally well tolerated, with low rates of anaemia and treatment discontinuation in non-cirrhotic previously untreated and previously treated patients with HCV genotype 4 infection.”

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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