

Treatment Experienced

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

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

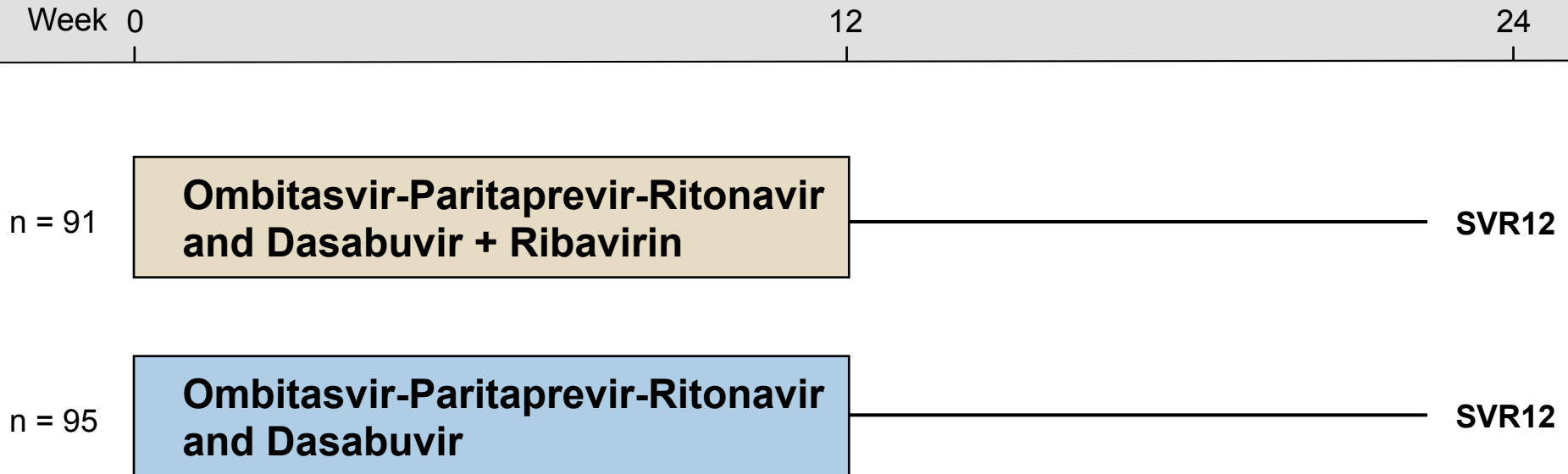
Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir +/- RBV in GT1b

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)

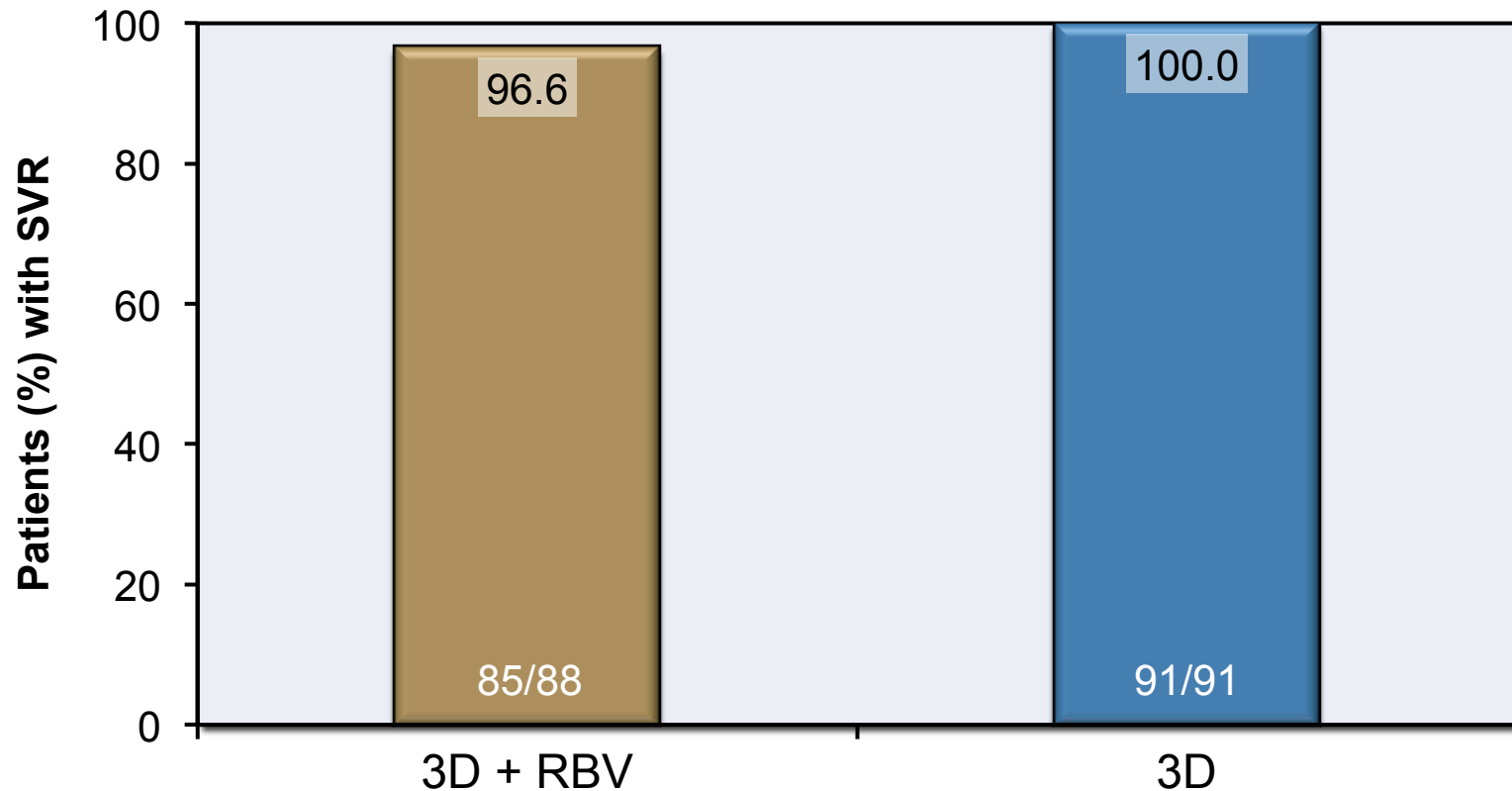
Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir +/- RBV in GT1b PEARL-II: Baseline Characteristics

| 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 ₁₀ IU/ml (mean) | 6.56 | 6.48 |
| Fibrosis score F3 (%) | 15.4 | 13.7 |

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

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

PEARL-II: SVR 12 Rates*

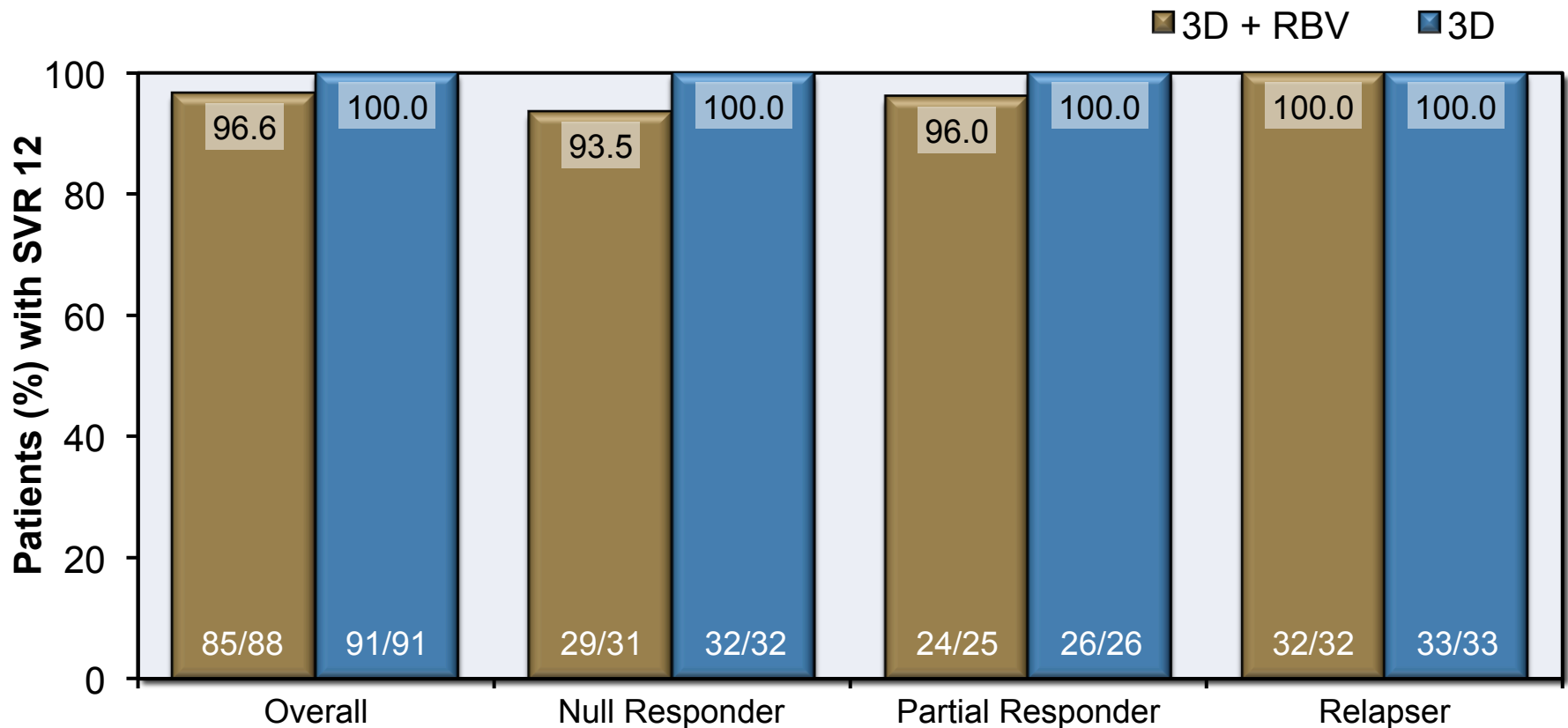


*Primary endpoint by intention-to-treat analysis

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

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

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/>

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