Treatment Experienced

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

PEARL-II

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

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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

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

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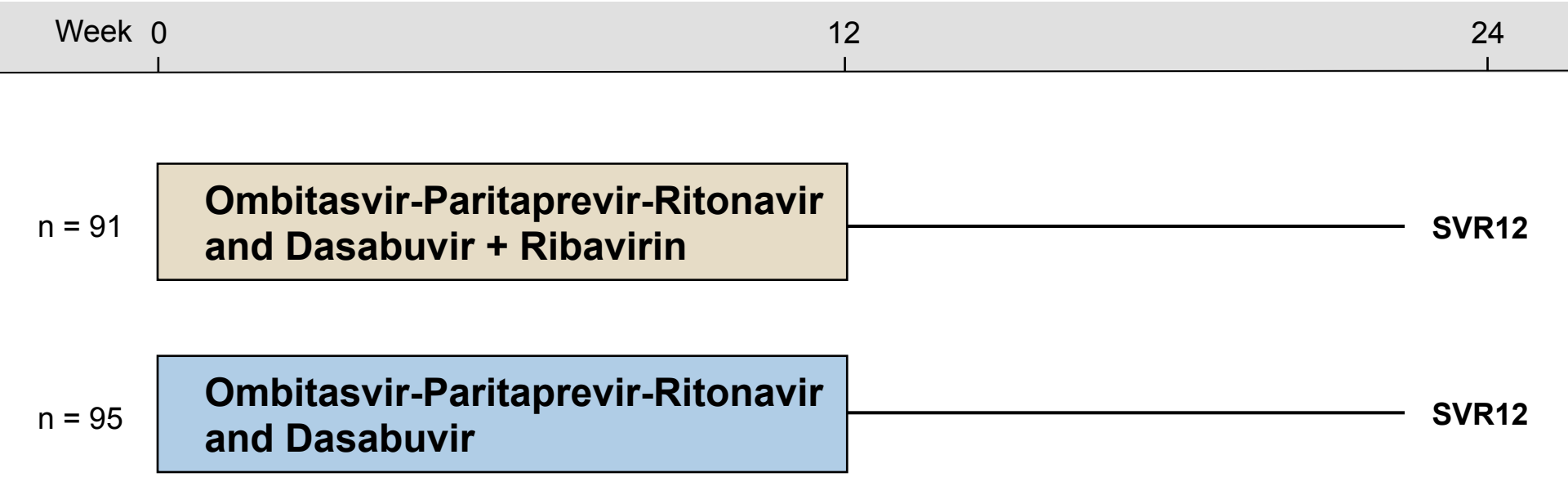
Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir +/- RBV in GT1b
PEARL-II: Regimens



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)

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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

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

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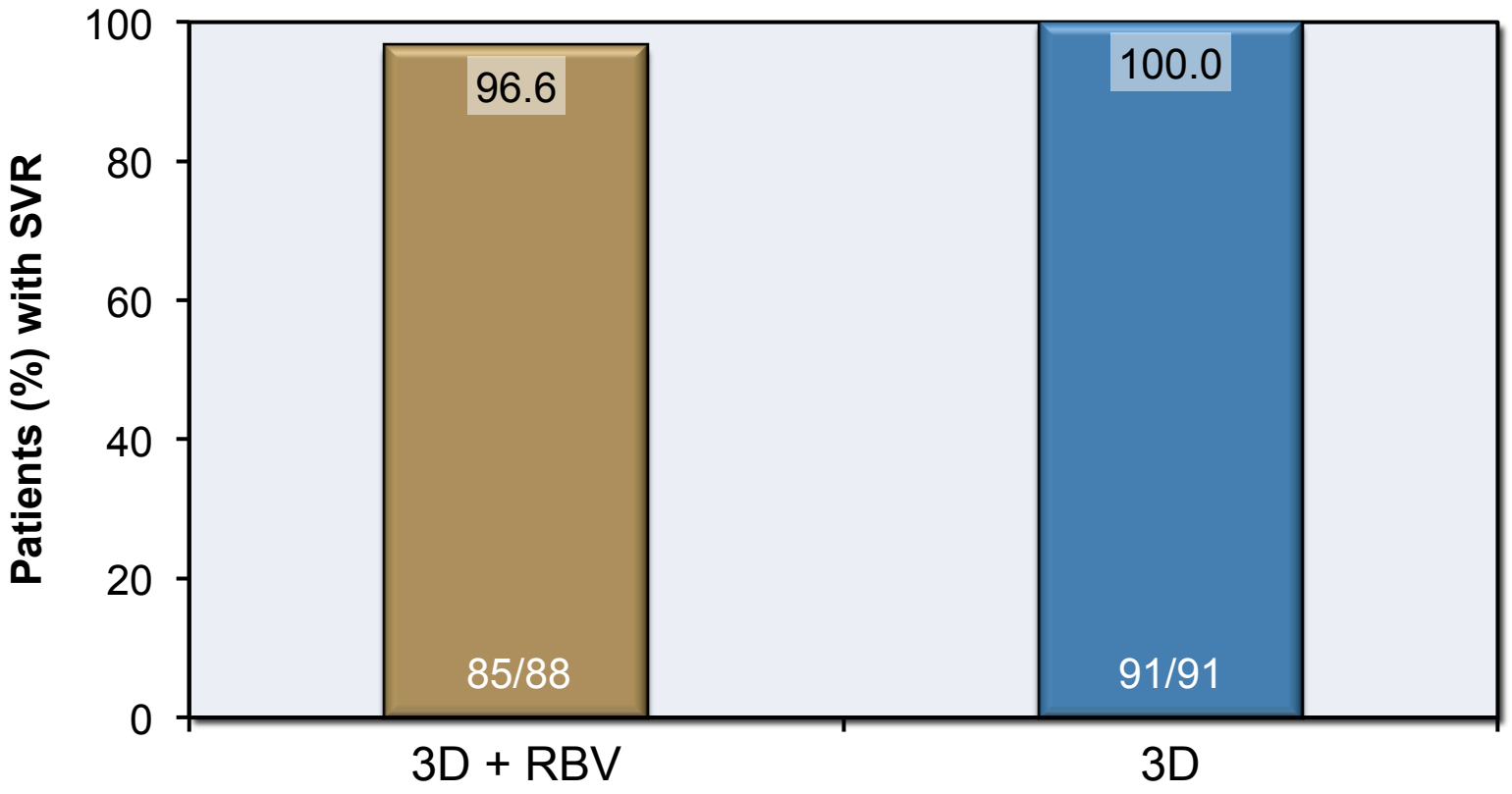
Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir +/- RBV in GT1b PEARL-II: Results

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.

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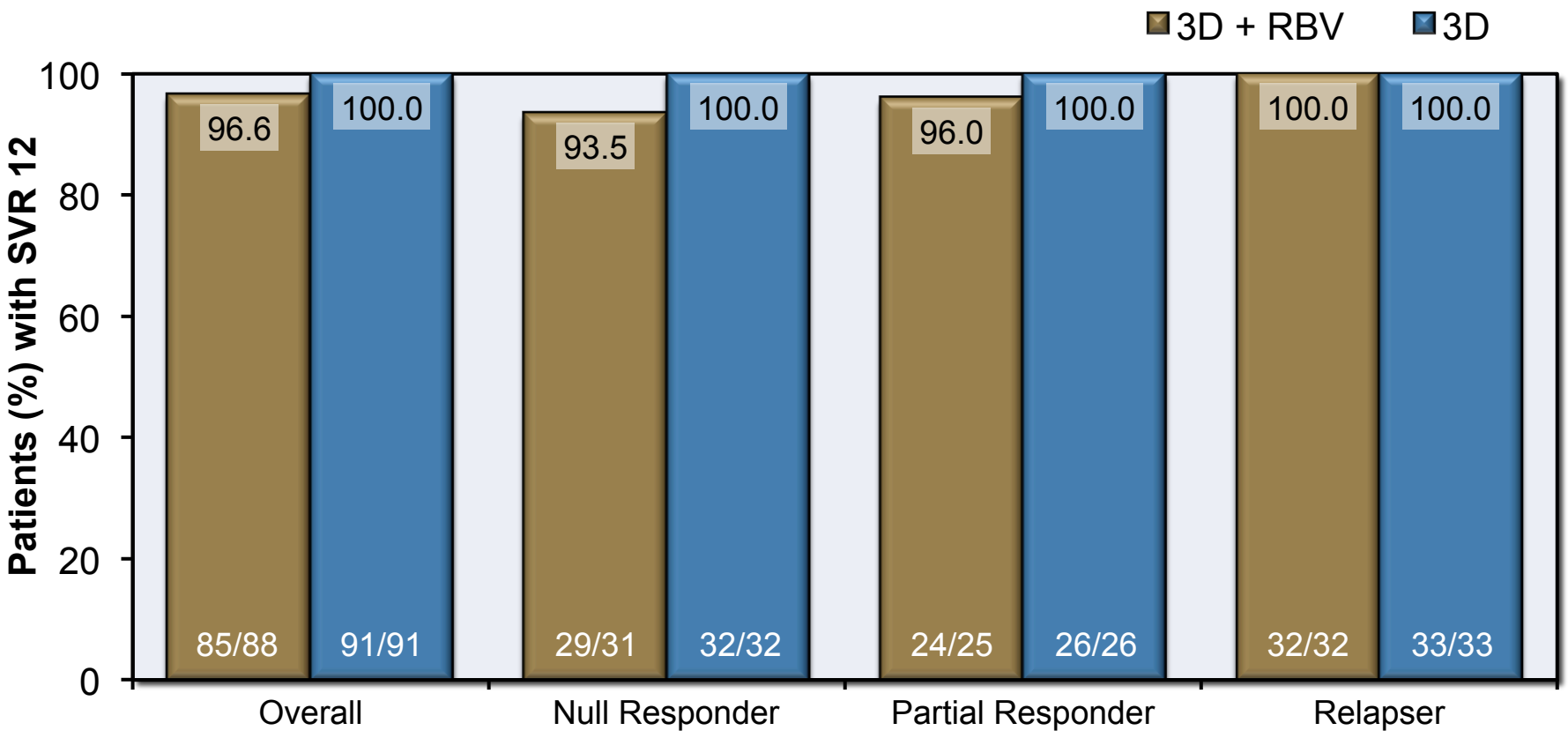
Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir +/- RBV in GT1b
PEARL-II: Results by Prior Treatment Response

PEARL-II: Results by Prior Treatment Response



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

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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

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

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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

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

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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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