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^2) +/- 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

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

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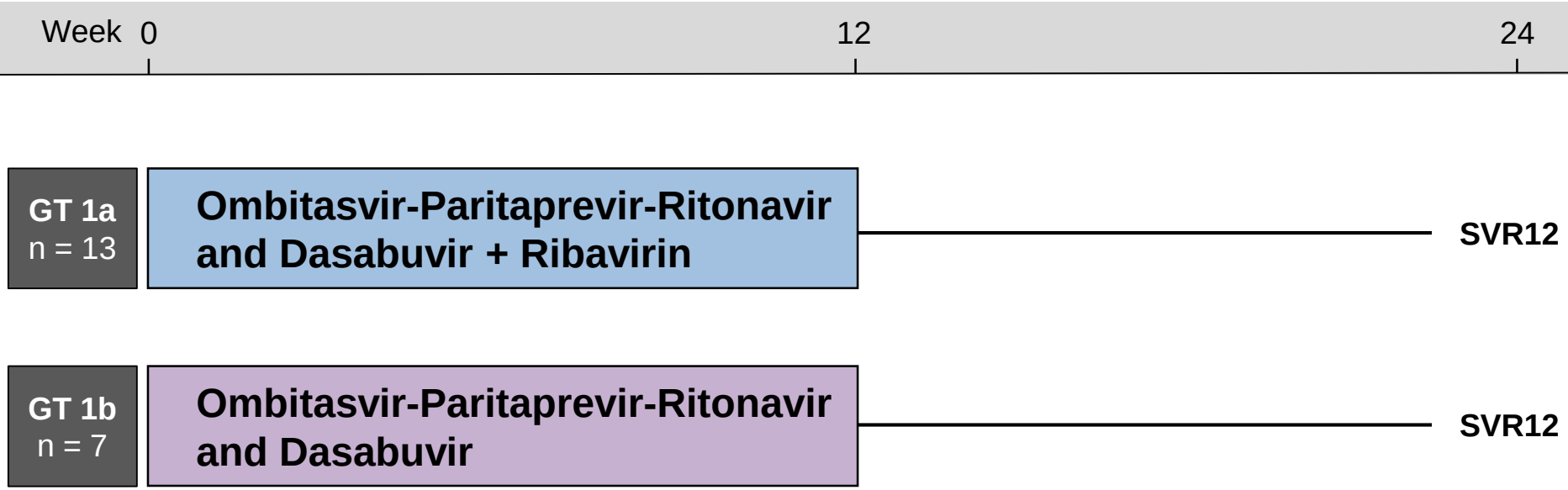
RUBY-I: Regimens



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

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RUBY-I: Baseline Characteristics

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

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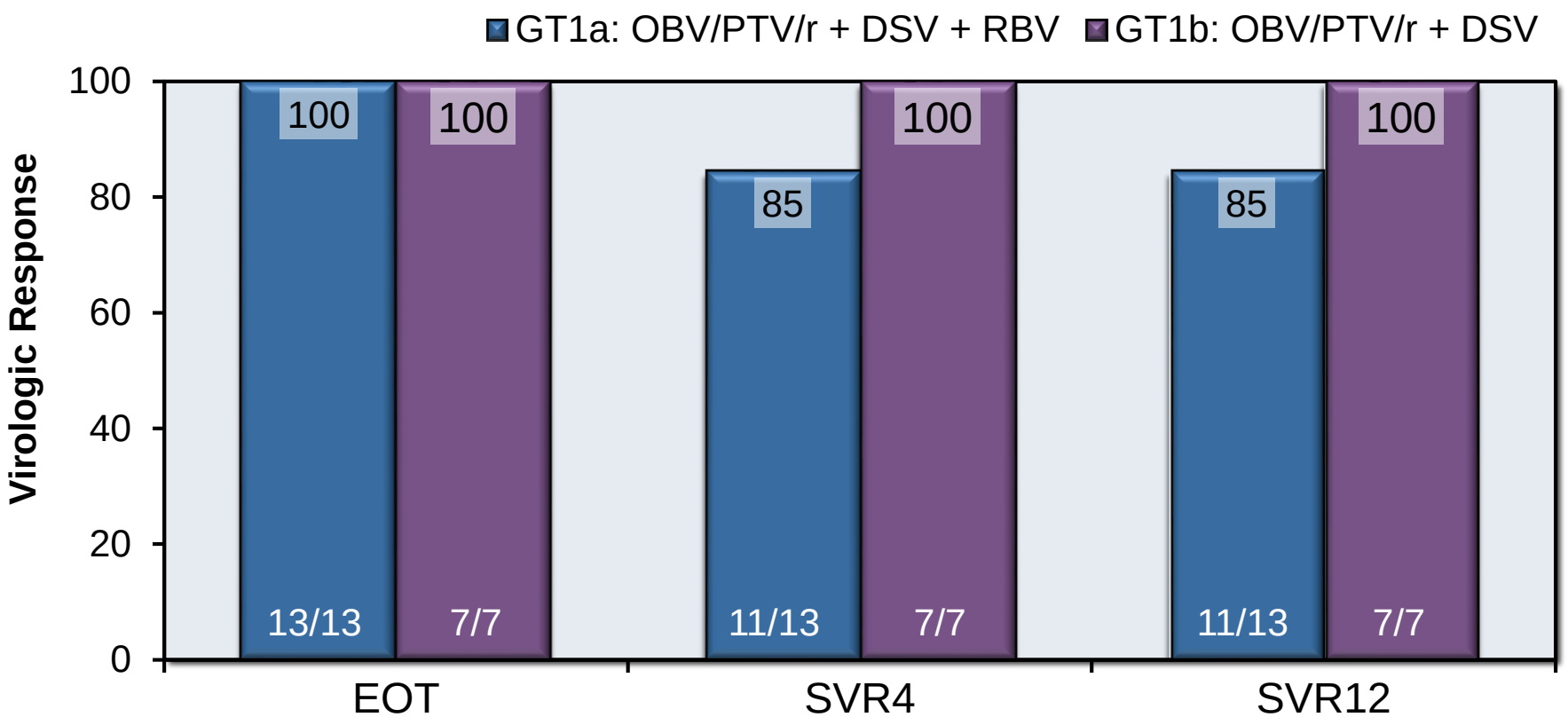
Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir in GT1 & Renal Disease
RUBY-I: Baseline Results

RUBY-I: SVR 12 Rates*



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

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

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.”

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

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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Hepatitis
web study