Phase 3

Treatment Naïve and Treatment Experienced

Compensated Cirrhosis

Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir in GT1b

TURQUOISE-III

Feld JJ, et al. J Hepatol. 2016;64:301-7.

Hepatitis web study

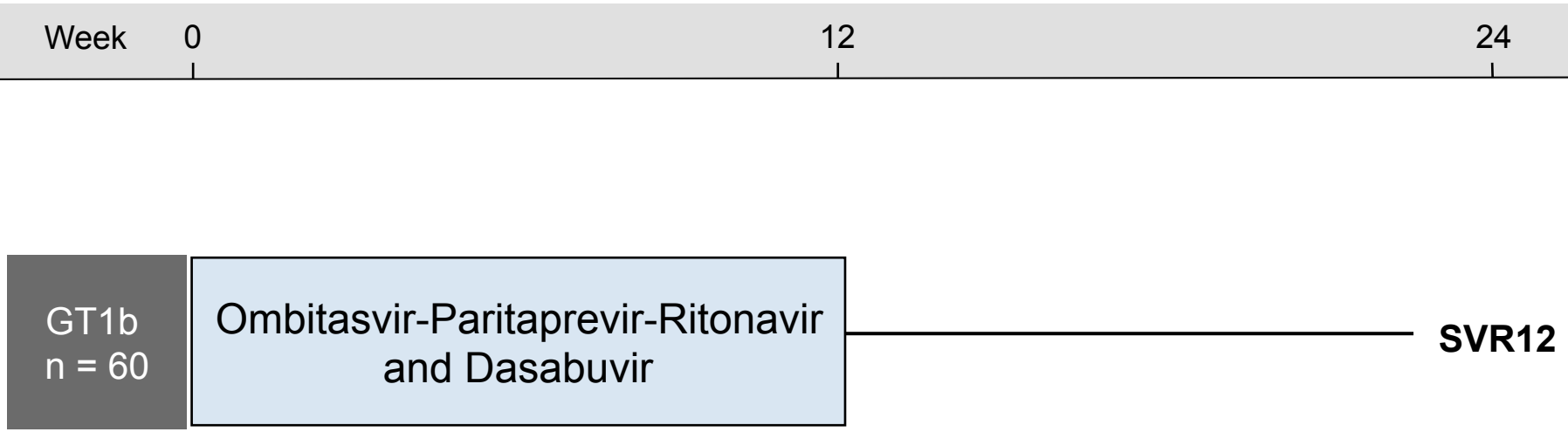
OMB-PTV-RTV + DSV in GT1b and Compensated Cirrhosis
TURQUOISE-III: Study Design

TURQUOISE-III: Features

- **Design**: Phase 3, open-label trial evaluating safety and efficacy of ombitasvir-paritaprevir-ritonavir and dasabuvir given for 12 weeks in treatment-naïve and treatment-experienced adults with chronic HCV GT 1b and compensated cirrhosis
- **Setting:** 19 sites in United States, Canada, and Belgium
- **Entry Criteria**
  - Chronic HCV infection with genotype 1b
  - Treatment-naïve or previously treated with peginterferon + ribavirin
  - Age ≥18 years
  - Plasma HCV RNA greater than 1,000 IU/mL
  - Documented cirrhosis Cirrhosis (Metavir >3, Ishak score >4 or Fibroscan ≥12.5 kPa)
  - Cirrhosis is compensated (Child-Pugh score <7 at screening)
  - Absence of coinfection with HBV or HIV
- **Primary End-Point**: SVR12

Source: Feld JJ, et al. J Hepatol. 2016;64:301-7.

OMB-PTV-RTV + DSV in GT1b and Compensated Cirrhosis
TURQUOISE-III: Study Design



Drug Dosing

Ombitasvir-Paritaprevir-Ritonavir (25/150/100 mg once daily) + Dasabuvir: 250 mg twice daily

Source: Feld JJ, et al. J Hepatol. 2016;64:301-7.

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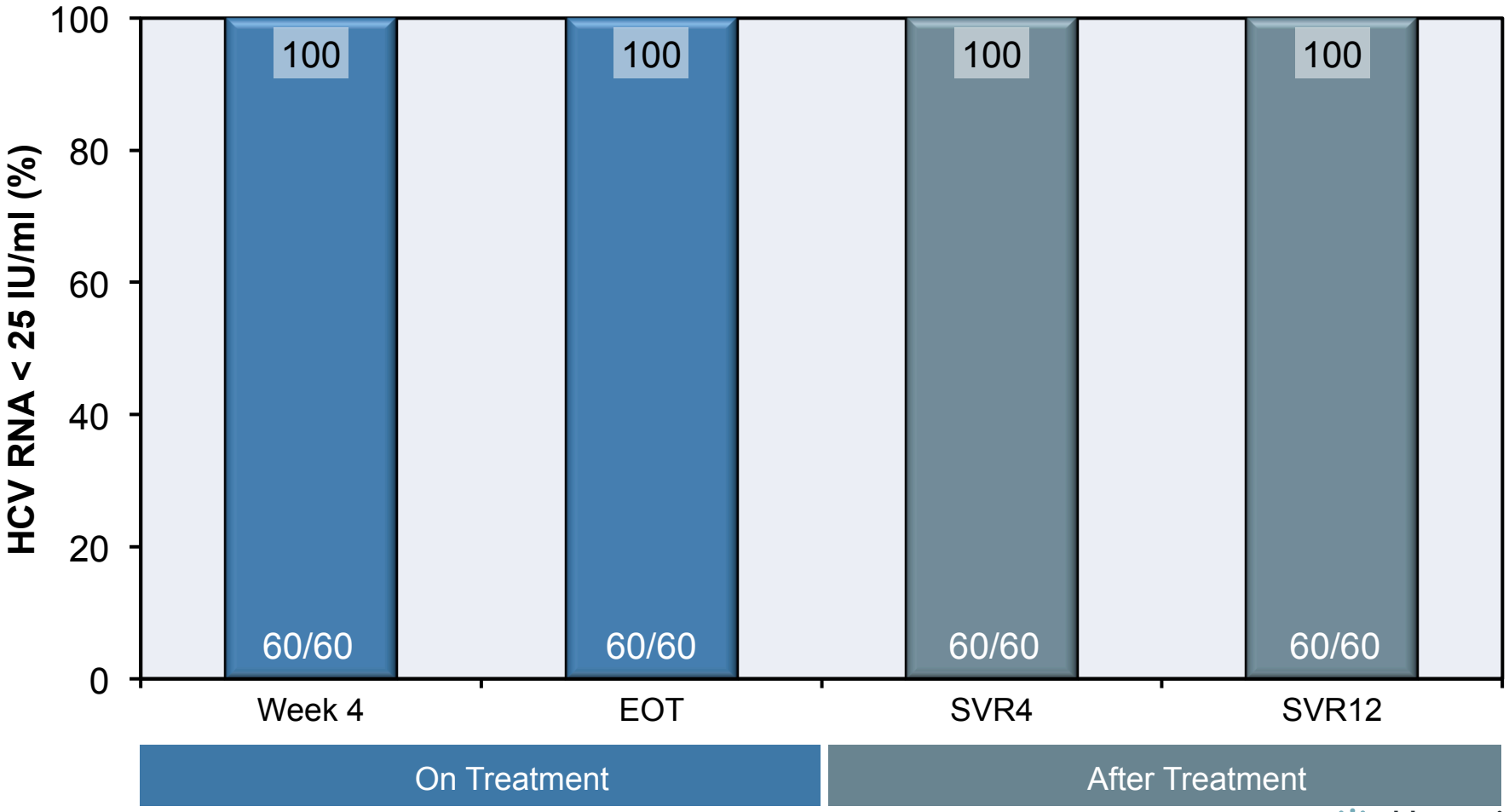
TURQUOISE-III: Results

Virologic Response to Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir



Source: Feld JJ, et al. J Hepatol. 2016;64:301-7.

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OMB-PTV-RTV + DSV in GT1b and Compensated Cirrhosis TURQUOISE-III: Adverse Effects

Common Adverse Events (≥10% of patients)	**OMB-PTV-RTV + DSV x 12 weeks** (n = 60)
Fatigue (%)	13 (21.7)
Diarrhea (%)	12 (20.0)
Headache (%)	11 (18.3)
Arthralgia (%)	6 (10.0)
Dizziness (%)	6 (10.0)
Insomnia (%)	6 (10.0)
Pruritis (%)	6 (10.0)

Abbreviations: OMB= Ombitasvir; PTV = Paritaprevir; RTV = Ritonavir; DSV= Dasabuvir

Source: Feld JJ, et al. J Hepatol. 2016;64:301-7.

OMB-PTV-RTV + DSV in GT1b and Compensated Cirrhosis TURQUOISE-III: Adverse Effects

Laboratory Abnormalities	OMB-PTV-RTV + DSV x 12 weeks (n = 60)
Hemoglobin(%)	13 (21.7)
Total bilirubin Grade 2 (>1.5-3 x ULN) Grade 3 (>3-10 x ULN)	 12 (20.0) 0
Alanine aminotransferase (%) Grade 3 (>5-20 x ULN)	 1 (1.7)
Aspartate aminotransferase (%) Grade 3 (>5-20 x ULN)	 0

Abbreviations: OMB= Ombitasvir; PTV = Paritaprevir; RTV = Ritonavir; DSV= Dasabuvir

Source: Feld JJ, et al. J Hepatol. 2016;64:301-7.

OMB-PTV-RTV + DSV in GT1b and Compensated Cirrhosis TURQUOISE-III: Conclusions

Conclusions: “The HCV regimen of ombitasvir/paritaprevir/ritonavir and dasabuvir without ribavirin for 12 weeks achieved 100% SVR12 and was well tolerated in HCV genotype 1b-infected patients with cirrhosis, suggesting that this 12-week ribavirin-free regimen is sufficient in this population.”

Source: Feld JJ, et al. J Hepatol. 2016;64:301-7.