Treatment-Naïve and Treatment-Experienced

Glecaprevir-Pibrentasvir in HCV GT 3, Without Cirrhosis
SURVEYOR-II (Part 3)

Source: Wyles D, et al. Hepatology. 2017 Sep 19. [Epub ahead of print]

Glecaprevir-Pibrentasvir in HCV GT 3, with Cirrhosis and Prior Treatment
SURVEYOR-II (Part 3): Study Features

SURVEYOR-II (Part 3) Trial

- **Design**: Open-label single-arm phase 3 trial to evaluate the safety and efficacy of the fixed-dose combination of glecaprevir-pibrentasvir for 8 weeks in treatment-naïve and treatment-experienced adults with GT 3 chronic HCV infection, without cirrhosis and with compensated cirrhosis
- **Setting**: U.S., Australia, Canada, France, New Zealand, and United Kingdom
- **Key Eligibility Criteria**
  - Chronic HCV GT 3
  - HCV RNA ≥1,000 IU/mL at screening
  - Treatment naïve
  - Prior treatment with (1) PEG (or INF) +/- RIB or (2) Sofosbuvir + RIB +/- PEG
  - Patients with compensated cirrhosis included
  - Patients with HIV or chronic HBV excluded
- **Primary End-Point**: SVR12

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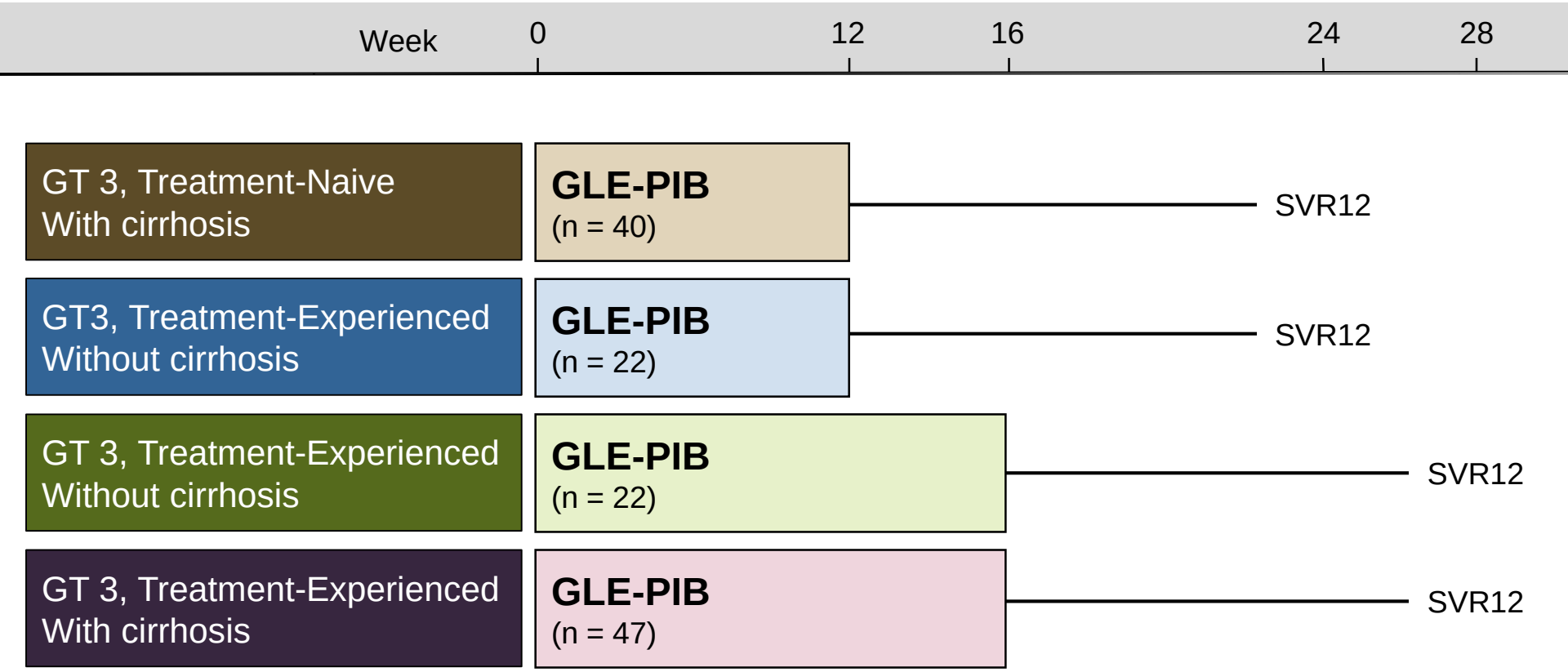
Glecaprevir-Pibrentasvir in HCV GT 3, with Cirrhosis and Prior Treatment
SURVEYOR-II (Part 3): Study Design



Drug Dosing: Glecaprevir-pibrentasvir (100/40 mg) fixed dose combination; three pills once daily

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Glecaprevir-Pibrentasvir in HCV GT 3, with Cirrhosis and Prior Treatment
SURVEYOR-II (Part 3): Baseline Characteristics

Baseline Characteristic	Arm A: 12 weeks GLE-PIB		Arm B: 16 weeks GLE-PIB	
	Naive (+) Cirrhosis (n = 40)	Experienced (-) Cirrhosis (n = 22)	Experienced (-) Cirrhosis (n = 22)	Experienced (+) Cirrhosis (n = 47)
Age, median years (range)	56 (36-70)	56 (35-68)	59 (29-66)	59 (47-70)
Male, n (%)	24 (60)	14 (64)	14 (64)	36 (77)
White race, n (%)	37 (93)	17 (77)	20 (91)	42 (89)
HCV RNA, median $\log_{10}$ IU/mL (range)	6.2 (4.2-7.1)	6.6 (5.1-7.5)	6.1 (4.7-7.3)	6.5 (4.6-7.2)
BMI, median SD, kg/m^2	29 (21-51)	26 (19-42)	28 (22-48)	27 (21-42)
Prior Treatment History, n (%)				
Naïve	40 (100)	0	0	0
IFN/PEG ± RBV, n (%)	0	14 (64)	13 (59)	22 (47)
SOF + RBV ± PEG, n (%)	0	8 (36)	9 (41)	25 (53)

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Glecaprevir-Pibrentasvir in HCV GT 3, Without Cirrhosis
SURVEYOR-II (Part 3): Baseline Characteristics

Prevalence of Baseline Amino Acid Polymorphisms* in NS3 or NS5A

Genotype	Prevalence of Baseline Polymorphism, n (%)			
	Naive (+) Cirrhosis (n = 40)	Experienced (-) Cirrhosis (n = 22)	Experienced (-) Cirrhosis (n = 22)	Experienced (+) Cirrhosis (n = 47)
Any	10 (26)	6 (27)	3 (14)	7 (15)
NS3 only	1 (3)	0	0	1 (2)
NS5A only	9 (23)	6 (27)	3 (14)	6 (13)
NS3 + NS5A	0	0	0	0

*Baseline polymorphisms detected by next generation sequencing at a 15% threshold in samples that had sequences available for both targets (N) at the following amino acid positions:
NS3: 155, 156, 168
NS5A: 24, 28, 30, 31, 58, 92, 93

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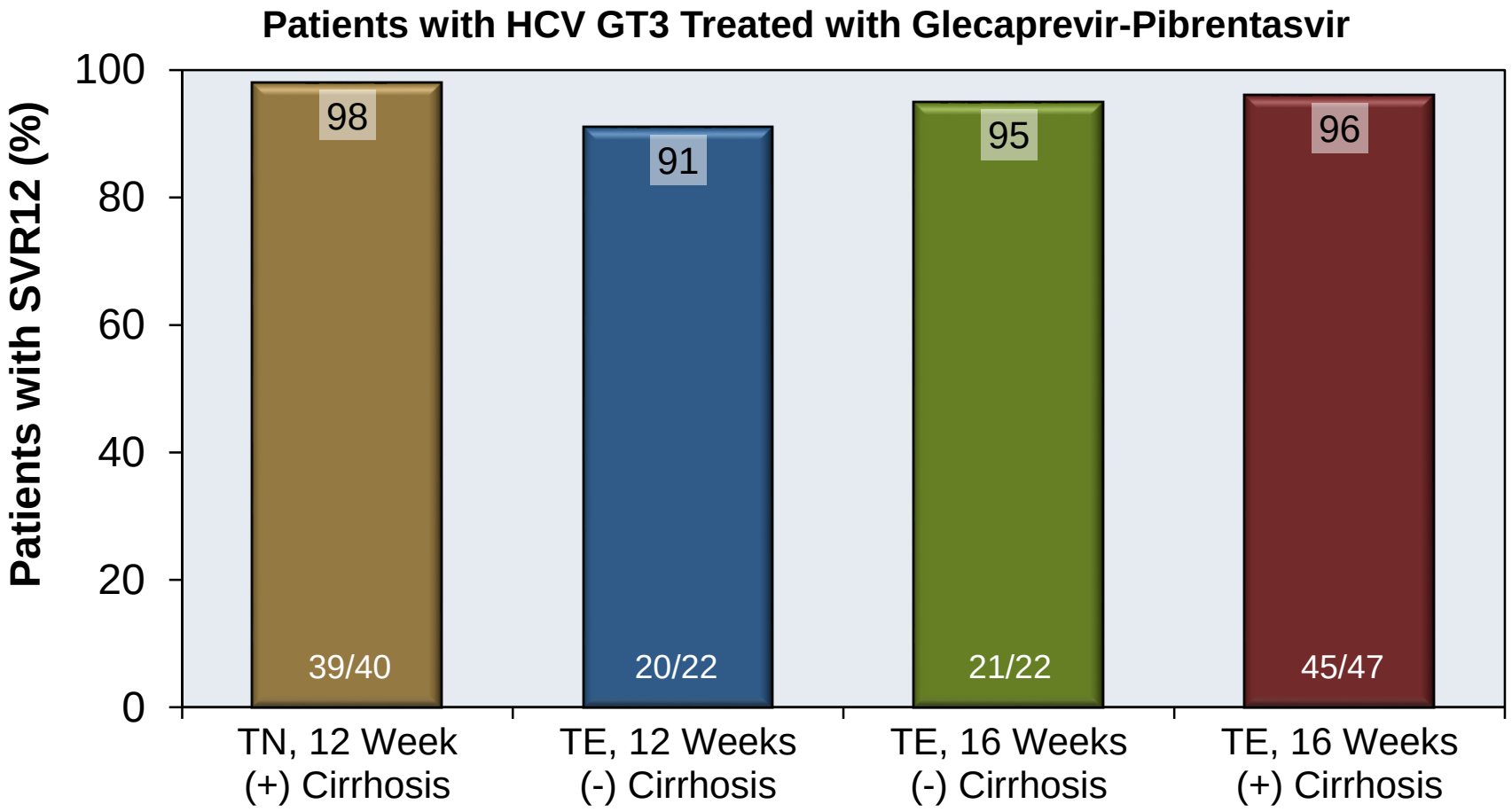
Glecaprevir-Pibrentasvir in HCV GT 3, with Cirrhosis and Prior Treatment
SURVEYOR-II (Part 3): Results



Abbreviations: TN = Treatment Naïve; TE = Treatment Experienced

Source: Wyles D, et al. Hepatology. 2017 Sep 19. [Epub ahead of print]

Glecaprevir-Pibrentasvir in HCV GT 3, with Cirrhosis and Prior Treatment
SURVEYOR-II (Part 3): Conclusions

Conclusion: “Patients with HCV GT3 infection with prior treatment experience and/or compensated cirrhosis achieved high SVR12 rates following 12 or 16 weeks of treatment with G/P. The regimen was well tolerated.”

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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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