Glecaprevir-Pibrentasvir in HCV GT 3, +/- Cirrhosis

SURVEYOR-II (Part 3)

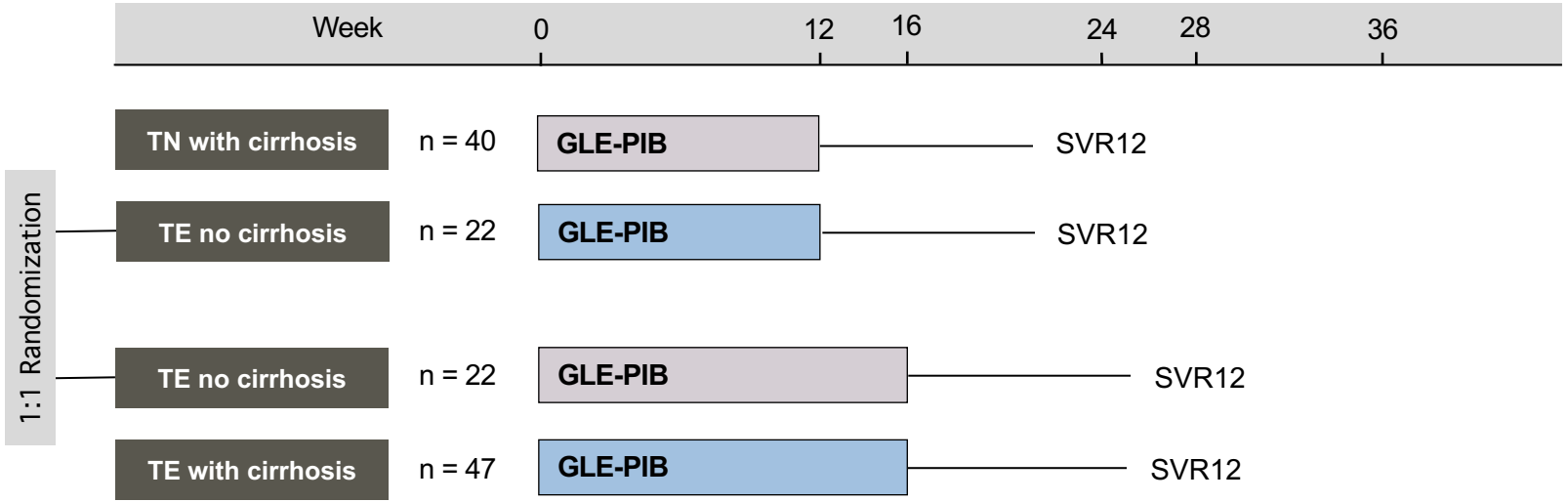
Source: Wyles D, et al. Hepatology. 2018;67:514-23.

Glecaprevir-Pibrentasvir for Retreatment in Patients with GT3 SURVEYOR-II, part 3: Study Features

- **Design**: Phase 3 partly randomized, open-label trial that assessed the safety and efficacy of glecaprevir-pibrentasvir for 12 or 16 weeks in patients with GT3, including those with prior treatment experience with sofosbuvir and/or compensated cirrhosis.
- **Setting:** United States, 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 or
  - 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
- **End Points**: Safety and efficacy, stratified by cirrhosis status

Source: Wyles D, et al. Hepatology;2018;67:514-523.

Glecaprevir-Pibrentasvir for Retreatment in Patients with GT3 SURVEYOR-II, part 3: Study Design



Abbreviations: GLE-PIB = glecaprevir-pibrentasvir; GT, genotype; TN = treatment-naïve; TE = treatment-experienced

Drug Dosing: Glecaprevir-pibrentasvir (300/120 mg), once daily

Source: Wyles D, et al. Hepatology;2018;67:514-23.

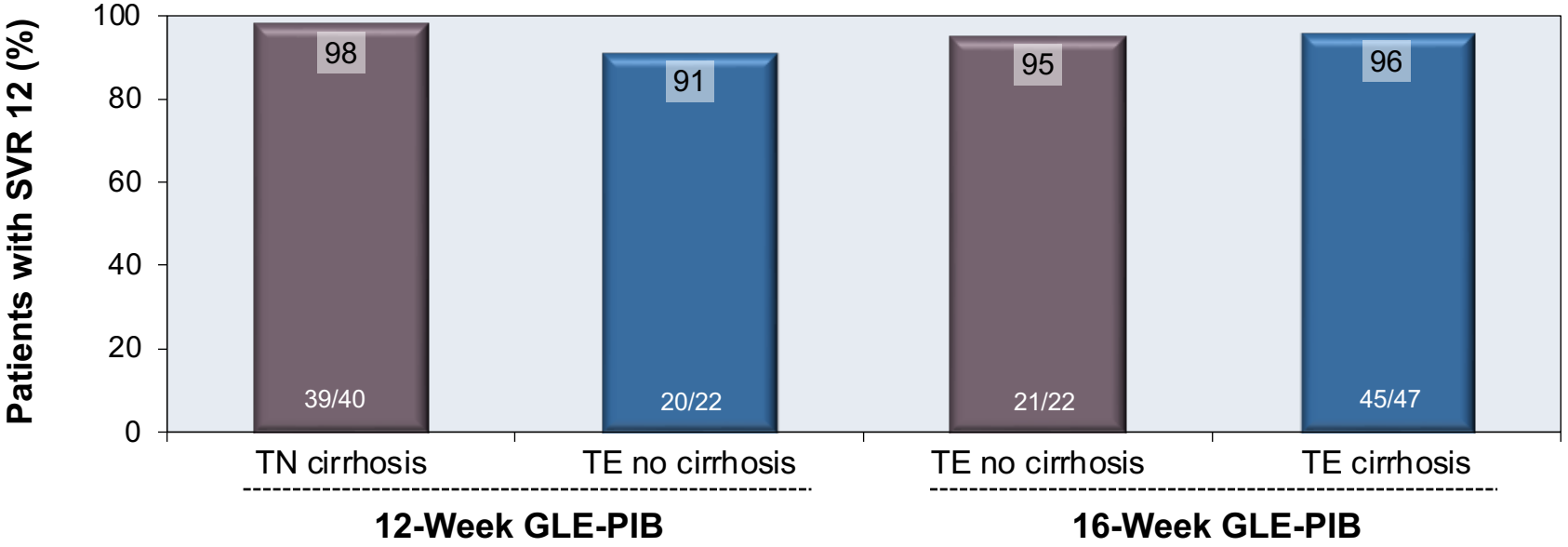
Glecaprevir-Pibrentasvir for Retreatment in Patients with GT3 SURVEYOR-II, part 3: Baseline Characteristics

Baseline Characteristic	12-Week GLE-PIB		16-Week GLE-PIB	
	TN w/ cirrhosis (n = 40)	TE no cirrhosis (n = 22)	TE no cirrhosis (n = 22)	TE w/ cirrhosis (n = 47)
Median age, y (range)	56 (36-70)	56 (35-68)	59 (29-66)	59 (47-70)
Male sex, n (%)	24 (60)	14 (64)	14 (64)	36 (77)
White race, n (%)	24 (60)	17 (77)	20 (91)	42 (89)
Cirrhosis, n (%) Child-Pugh score 5 Child-Pugh score 6	 35 (88) 5 (13)	 0	 0	 37 (79) 10 (21)
BMI, kg/m^2 median (range)	29 (21-51)	26 (19-42)	28 (22-48)	27 (21-42)
HCV RNA, $\log_{10}$ IU/mL median (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)
Prior treatment history, n (%) IFN/pegIFN ± RBV SOF + RBV ± pegIFN	 0 0	 14 (64) 8 (36)	 13 (59) 9 (41)	 22 (47) 25 (53)
Baseline polymorphisms, n (%) Any NS3 only NS5A only Both NS3 + NS5A	 10 (26) 1 (3) 9 (23) 0	 6 (27) 0 6 (27) 0	 3 (14) 0 3 (14) 0	 7 (15) 1 (2) 6 (13) 0

Source: Wyles D, et al. Hepatology;2018;67:514-23.

Glecaprevir-Pibrentasvir for Retreatment in Patients with GT3 SURVEYOR-II, part 3: Results

SURVEYOR-II, part 3: SVR 12* by Treatment Duration and Subgroup

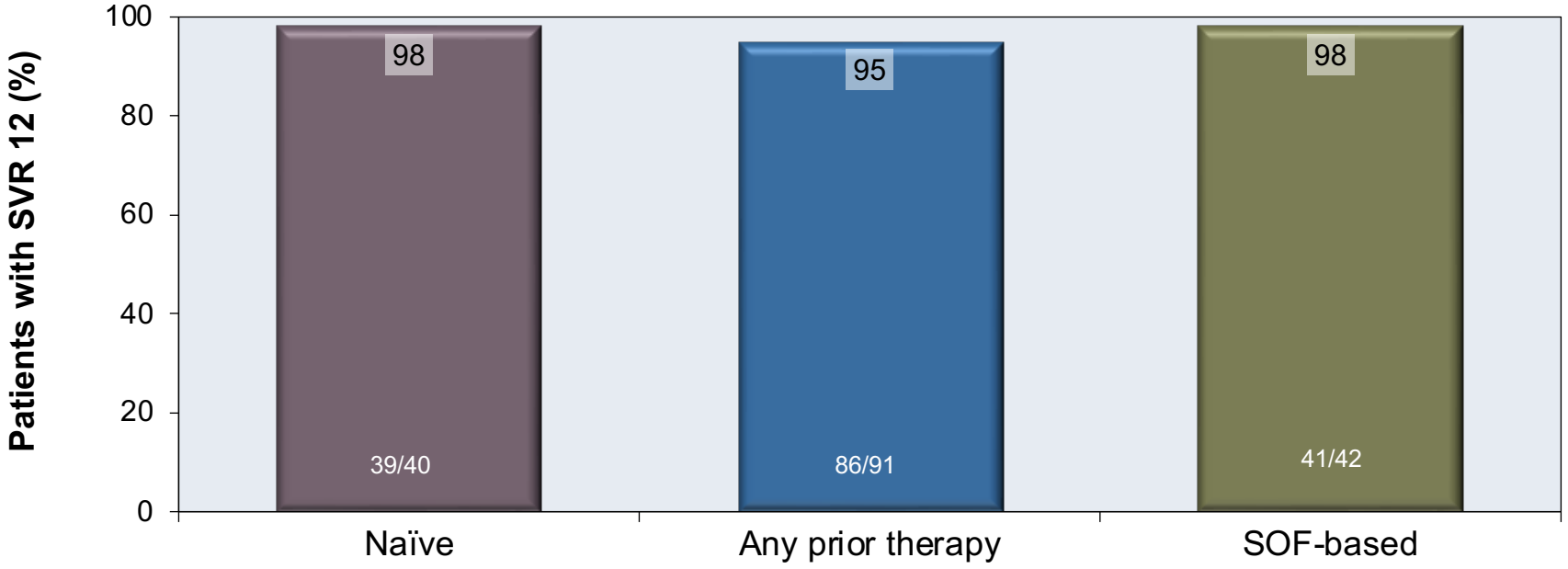


Abbreviations: GLE-PIB, glecaprevir-pibrentasvir
* Primary end-point by intention-to-treat analysis

Source: Wyles D, et al. Hepatology;2018;67:514-523.

Glecaprevir-Pibrentasvir for Retreatment in Patients with GT3 SURVEYOR-II, part 3: Results

SURVEYOR-II, part 3: SVR12 by Treatment Experience



Source: Wyles D, et al. Hepatology;2018;67:514-523.

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

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.”

Source: Wyles D, et al. Hepatology. 2018;67:514-23.

Acknowledgments

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