Glecaprevir-Pibrentasvir in Genotype 5 or 6
ENDURANCE-5,6

Source: Asselah T, et al. Lancet Gastroenterol Hepatol. 2019;4:45-51.

Glecaprevir-Pibrentasvir in Genotype 5 or 6
ENDURANCE-5,6: Study Features

- **Design**: Open-label, single-arm, phase 3b trial to evaluate the safety and efficacy of the fixed-dose combination of glecaprevir-pibrentasvir for 8 or 12 weeks in treatment-naïve and treatment-experienced adults with GT 5 or 6 chronic HCV infection with and without cirrhosis
- **Setting:** 24 clinics in Europe, N. America, Oceania, South Africa, SE Asia
- **Key Eligibility Criteria**
  - Chronic HCV GT 5 or 6
  - HCV RNA ≥1,000 IU/mL at screening
  - Naïve or treated with (1) PEG (or IFN) +/- RBV or (2) SOF + RBV +/- PEG
  - Compensated cirrhosis permitted (Child-Pugh score >6 excluded)
  - HIV or chronic HBV coinfection excluded
- **Primary End Point**: SVR12

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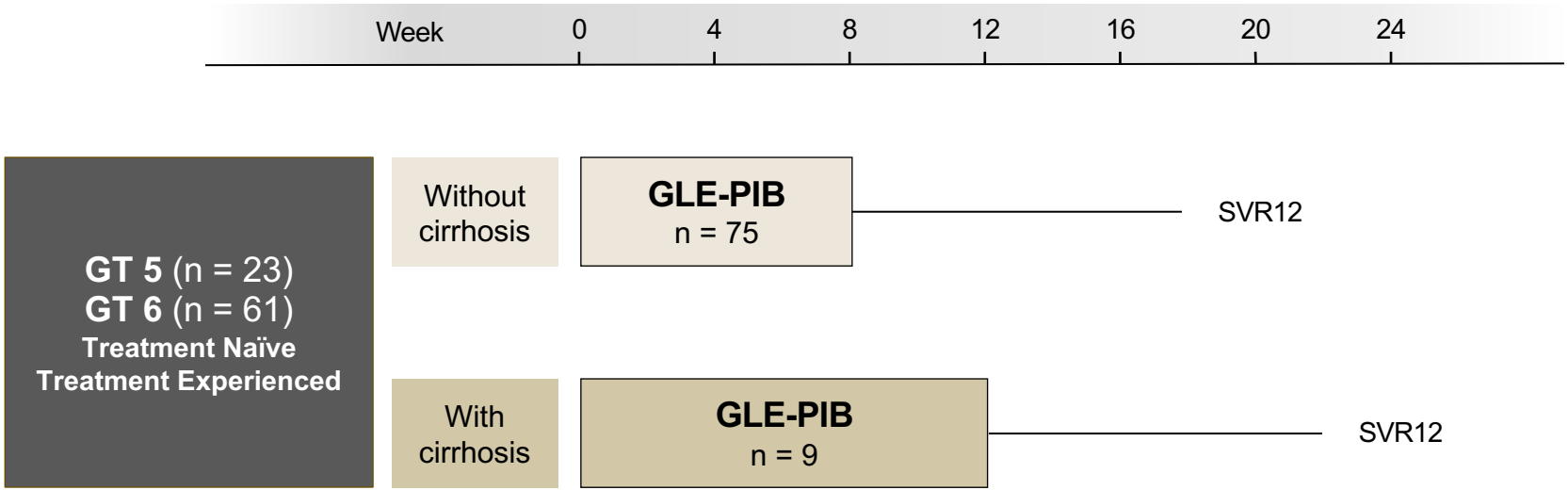
Glecaprevir-Pibrentasvir in Genotype 5 or 6 ENDURANCE-5,6: Study Design



Abbreviations: GLE-PIB= Glecaprevir-pibrentasvir

Drug Dosing: Glecaprevir-pibrentasvir (100/40 mg) fixed-dose combination; three pills (300/120 mg) once daily

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Glecaprevir-Pibrentasvir in Genotype 5 or 6 ENDURANCE-5,6: Baseline Characteristics

Baseline Characteristic	GT 5 (n = 23)	GT 6 (n = 61)
Age, median (range)	68 (24-76)	54 (30-79)
Male, n (%)	10 (43)	29 (48)
Race, n (%)		
White	21 (91)	4 (7)
Black	1 (4)	0
Asian	1 (4)	56 (92)
from Vietnam	0	9 (15)
from China	0	7 (11)
from Cambodia	0	0
Multirace	0	1 (2)
BMI, median (range), kg/m^2	27 (20-33)	24 (17-40)
Past Injection Drug Use, n (%)	0	5 (8)

*Last use >12 months ago

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Glecaprevir-Pibrentasvir in Genotype 5 or 6 ENDURANCE-5,6: Baseline Characteristics

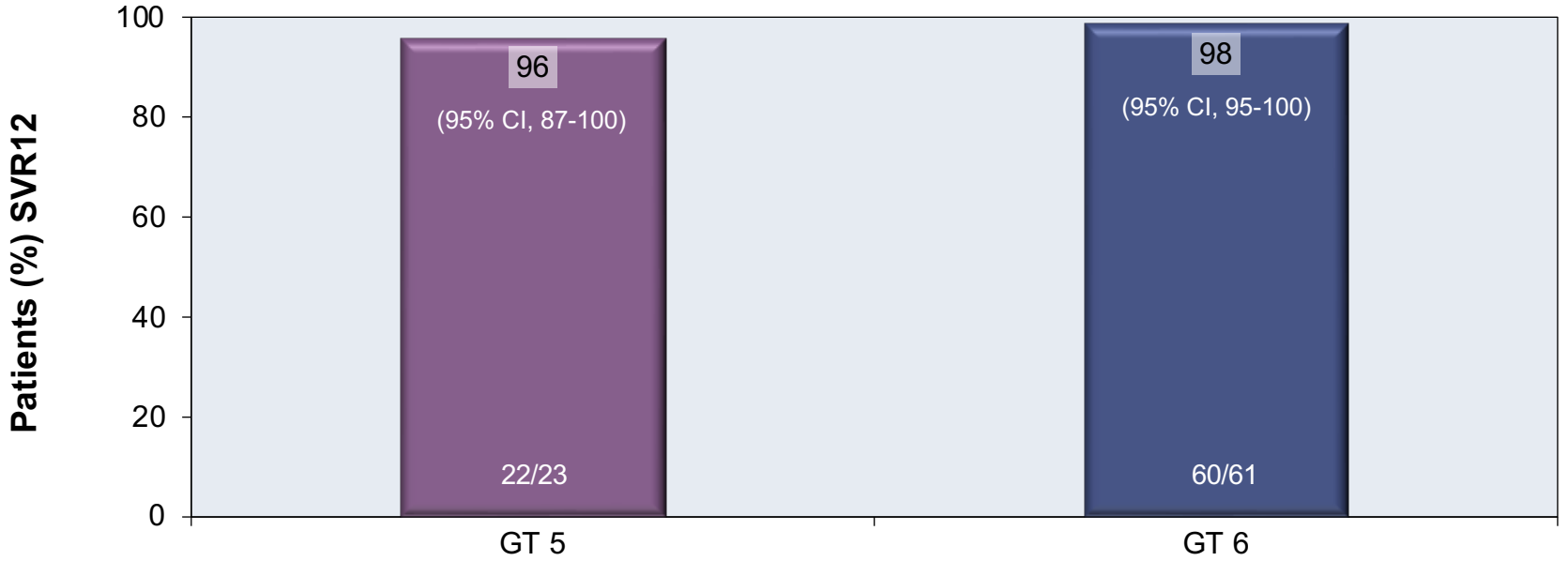
Baseline Characteristic	GT 5 (n = 23)	GT 6 (n = 61)
HCV RNA ≥1,000 IU/mL, n (%)	20 (87)	53 (87)
HCV treatment experienced*, n (%)	10 (43)	29 (48)
Race, n (%)		
F0-F1	17 (74)	45 (74)
F2	3 (13)	1 (2)
F3	0	9 (15)
F4/with cirrhosis	3 (13)	6 (10)
Baseline polymorphisms		
NS3 only	11/23 (48)	0
NS5A only	1/23 (4)	32/55 (58)
NS3 and NS5A	2/23 (9)	2/55 (4)
None	9/23 (39)	21/55 (38)

*No patient previously treated with sofosbuvir.

Source: Asselah T, et al. Lancet Gastroenterol Hepatol. 2019;4:45-51.

Glecaprevir-Pibrentasvir in Genotype 5 or 6 ENDURANCE-5,6: Results

ENDURANCE-5, 6: Overall SVR, by Genotype



Both patients with treatment failure had compensated cirrhosis and were adherent. GT 5 patient had subtype 5a and viral relapse. GT 6 patient had subtype 6f had on-treatment virologic failure by week 12.

Source: Asselah T, et al. Lancet Gastroenterol Hepatol. 2019;4:45-51.

Glecaprevir-Pibrentasvir in Genotype 5 or 6 ENDURANCE-5,6: Adverse Events

Adverse Events (AEs), n (%)	Glecaprevir-Pibrentasvir (n = 84)
Any adverse event	46 (55)
Grade 1 adverse event	24 (52)
AEs leading to drug discontinuation	0
Serious AEs	5 (6)[§]
AEs occurring in ≥10% of patients	
Fatigue	11 (13)
Headache	11 (13)
Laboratory AEs	
AST grade ≥3 (>5 x ULN)	0
ALT grade ≥3 (>5 x ULN)	0
Total bilirubin grade ≥3 (>3 x ULN)	0

[§]No serious AE considered related to study drug.

Source: Asselah T, et al. Lancet Gastroenterol Hepatol. 2019;4:45-51.

Glecaprevir-Pibrentasvir in Genotype 5 or 6 ENDURANCE-5,6: Conclusions

Interpretation: “Glecaprevir/pibrentasvir achieved high SVR12 rates, comparable with data reported in registrational studies, and was well tolerated in patients with HCV genotype 5 or 6 infection with compensated liver disease.”

Source: Asselah T, et al. Lancet Gastroenterol Hepatol. 2019;4:45-51.

Acknowledgments

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