Glecaprevir-Pibrentasvir in Non-Cirrhotic Genotype 4, 5, or 6
ENDURANCE-4

Source: Asselah T, et al. Clin Gastroenterol Hepatol. 2018;16:417-26.

Glecaprevir-Pibrentasvir in Non-Cirrhotic Genotype 4, 5, or 6 *ENDURANCE-4: Study Features

- **Design**: Open-label single-arm phase 3 trial to evaluate the safety and efficacy of the fixed-dose combination of glecaprevir-pibrentasvir for 12 weeks in treatment-naïve and treatment-experienced adults with GT 4, 5, or 6 chronic HCV infection without cirrhosis
- **Setting:** Canada, Europe, and South Africa
- **Key Eligibility Criteria**
  - Chronic HCV GT 4, 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
  - No cirrhosis
  - HIV or chronic HBV coinfection excluded
- **Primary End Point**: SVR12

***Note**: ENDURANCE-4 was published in conjunction with ENDURANCE-2 and SURVEYOR-II (Part 4)

Source: Asselah T, et al. Clin Gastroenterol Hepatol. 2018;16:417-26.

Glecaprevir-Pibrentasvir in Non-Cirrhotic Genotype 4, 5, or 6
ENDURANCE-4: Baseline Characteristics

Baseline Characteristic	Glecaprevir-Pibrentasvir (n = 121)
Fibrosis Stage, n (%) F0-1 F2 F3	 104 (86) 8 (7) 9 (7)
HCV Treatment-Naïve, n (%)	82 (68)
Treatment-Experienced, n (%) IFN or PEG ± RBV, n (%) SOF + RBV ± PEG, n (%)	39 (32) 39 (32) 0 (0)
Concomitant PPI use, n (%)	11 (9)

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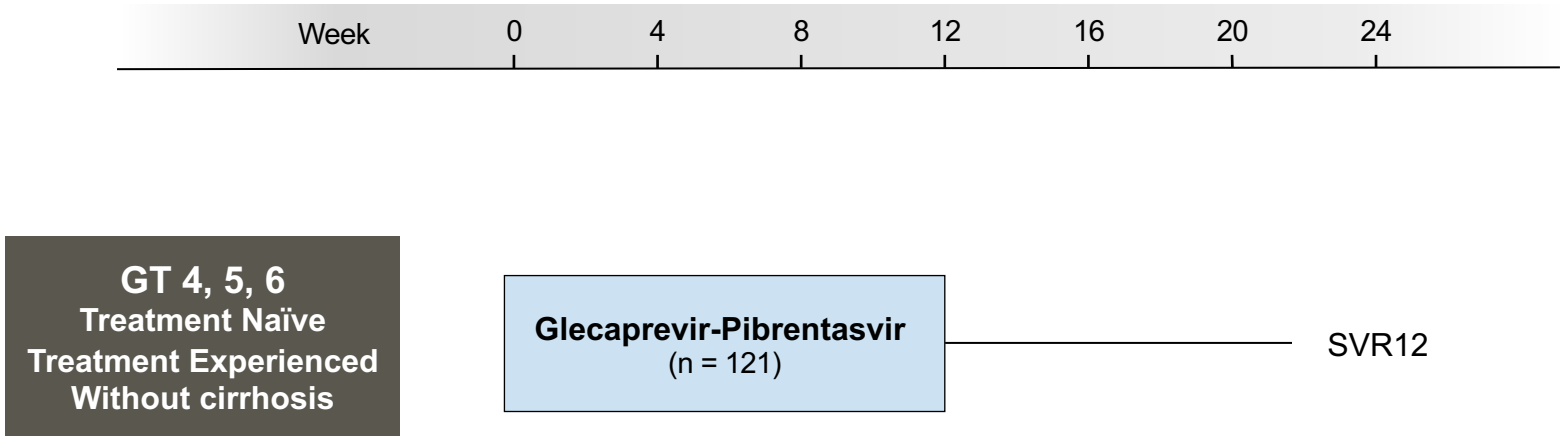
Glecaprevir-Pibrentasvir in Non-Cirrhotic Genotype 4, 5, or 6 ENDURANCE-4: Study Design



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

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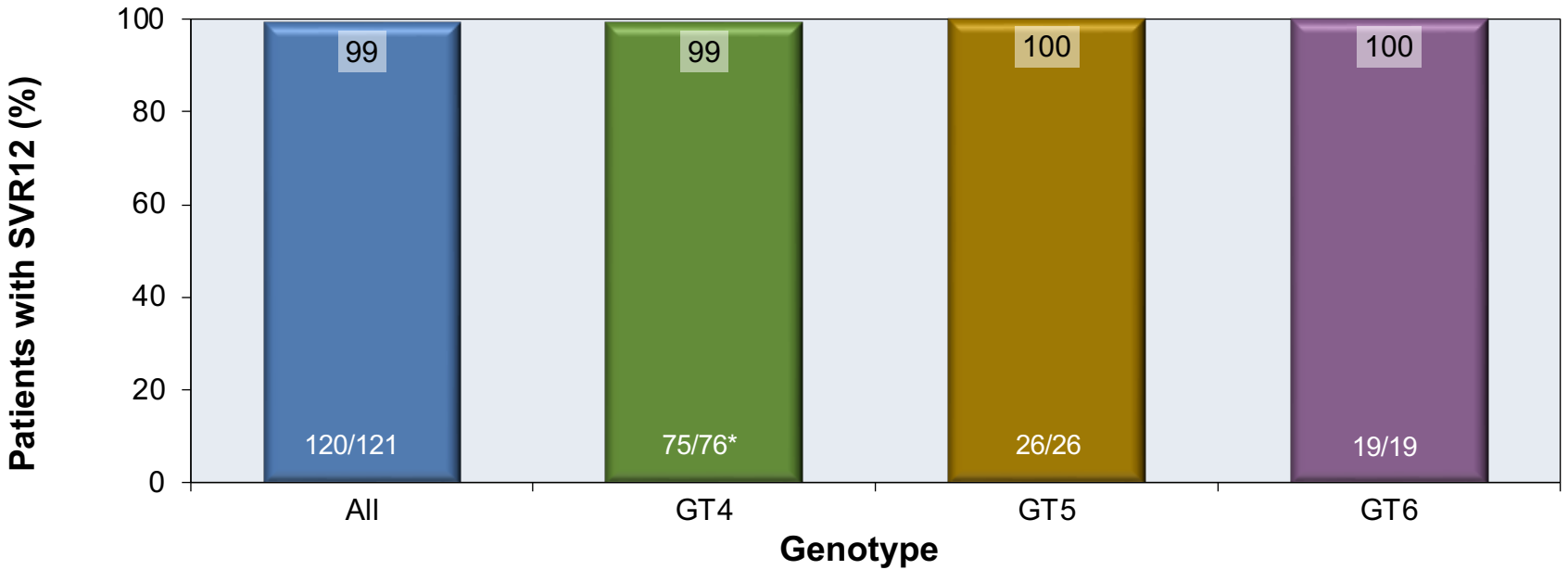
Glecaprevir-Pibrentasvir in Non-Cirrhotic Genotype 4, 5, or 6 ENDURANCE-4: Baseline Characteristics

Baseline Characteristic	Glecaprevir-Pibrentasvir (n = 121)
Age, mean ± SD, years	53 ± 11.0
Male, n (%)	77 (64)
Race, n (%)	
White	84 (71)
Black	10 (8)
Asian	24 (20)
BMI, mean, ± SD kg/m^2	25.7 ± 4.8
IL28B genotype non-CC, n (%)	91 (75)
HCV Genotype, n (%)	
4	76 (63)
5	26 (21)
6	19 (16)
HCV RNA, median (range), log_{10} IU/mL	6.3 (3.6-7.3)
Former IDU, n (%)	32 (26)

Source: Asselah T, et al. Clin Gastroenterol Hepatol. 2018;16:417-26.

Glecaprevir-Pibrentasvir in Non-Cirrhotic Genotype 4, 5, or 6 ENDURANCE-4: Results

SVR12 (ITT analysis), Overall and by Genotype



*1 patient stopped drug on day 12

Source: Asselah T, et al. Clin Gastroenterol Hepatol. 2018;16:417-26.

Glecaprevir-Pibrentasvir in Non-Cirrhotic Genotype 4, 5, or 6 ENDURANCE-4: Adverse Events

Adverse Events (AEs), n (%)	Glecaprevir-Pibrentasvir (n = 121)
AEs leading to drug discontinuation	3 (2.5)*
Serious AEs	1 (0.8)§
AEs occurring in ≥10% of patients	
Fatigue	21 (17)
Headache	25 (21)
Laboratory AEs	
AST grade ≥2 (>3x ULN)	0
ALT grade ≥2 (>3x ULN)	0
Total bilirubin grade ≥3 (>3x ULN)	0

*One patient with anxiety, another with heartburn, third with transient ischemic attack (TIA).
§Patient with baseline risk factors discontinued drug on day 12 due to TIA.

Source: Asselah T, et al. Clin Gastroenterol Hepatol. 2018;16:417-26.

Glecaprevir-Pibrentasvir in Non-Cirrhotic Genotype 4, 5, or 6 *ENDURANCE-4: Conclusions

Conclusion: “In 3 Phase 3 studies, 8 weeks' treatment with glecaprevir/pibrentasvir produced an SVR12 in at least 93% of patients with chronic HCV genotype 2, 4, 5, or 6 infection without cirrhosis, with virologic failure in less than 1%. The drug combination had a safety profile comparable to 12 week's treatment with glecaprevir/pibrentasvir.”

***Note**: ENDURANCE-4 was published in conjunction with ENDURANCE-2 and SURVEYOR-II (Part 4)

Source: Asselah T, et al. Clin Gastroenterol Hepatol. 2018;16:417-26.

Acknowledgments

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