Glecaprevir-Pibrentasvir in GT 1-6 and Compensated Cirrhosis
EXPEDITION-8

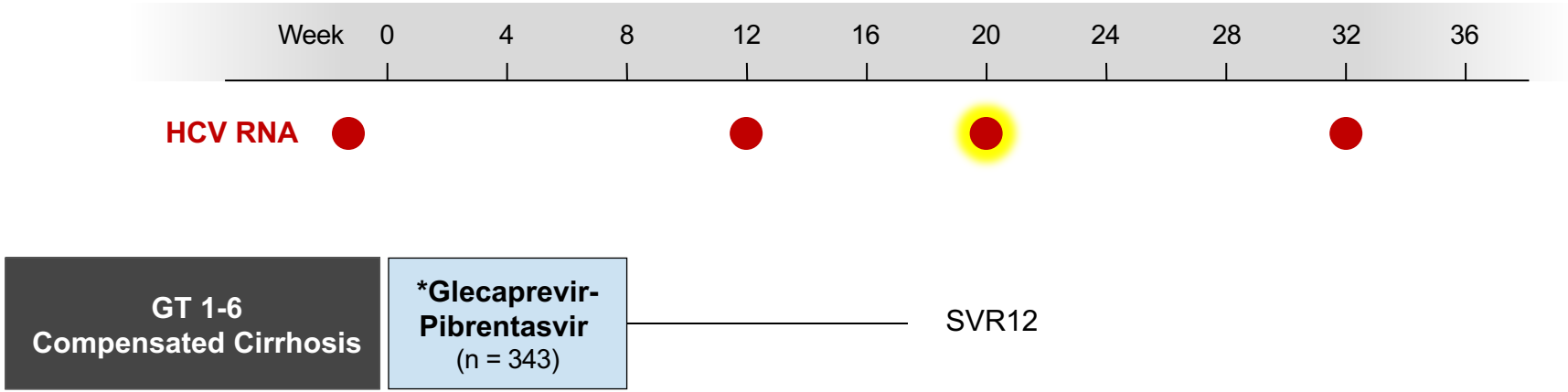
Source: Brown RS, et al. J Hepatol. 2020;72:441-8.

Glecaprevir-Pibrentasvir in GT 1-6 & Compensated Cirrhosis
EXPEDITION-8: Design

- **Design**: Single-arm, multicenter phase 3b trial to evaluate the efficacy of the fixed-dose combination of glecaprevir-pibrentasvir for 8 weeks in treatment-naïve participants with GT 1, 2, 3, 4, 5, or 6 chronic HCV and compensated cirrhosis
- **Setting:** 94 international sites
- **Key Eligibility Criteria**
  - Age ≥18 years
  - Chronic HCV GT 1, 2, 3, 4, 5, or 6
  - Compensated cirrhosis by (a) biopsy, (b) FibroScan, or (c) FibroTest + APRI
  - HCV RNA ≥1,000 IU/mL at screening
  - Treatment-naïve
  - Child-Pugh Score 5 or 6
  - Excluded: HIV or HBV or current/past decompensated cirrhosis
- **Primary End Point**: SVR12

Source: Brown RS, et al. J Hepatol. 2020;72:441-8.

Glecaprevir-Pibrentasvir in GT 1-6 & Compensated Cirrhosis
EXPEDITION-8: Treatment Protocol



*__Drug Dosing__: Glecaprevir-pibrentasvir (100/40 mg) fixed-dose combination, 3 pills once daily

Source: Brown RS, et al. J Hepatol. 2020;72:441-8.

Glecaprevir-Pibrentasvir in GT 1-6 & Compensated Cirrhosis
EXPEDITION-8: Baseline Characteristics

Baseline Characteristic	Glecaprevir-Pibrentasvir (n = 343)
Mean age (range), years	58 (51-65)
Male sex, n (%)	217 (63)
Race, n (%) White Black	 285 (83) 258 (8)
Hispanic or Latino ethnic origin, n (%)	43 (13)
Baseline Child-Pugh Score, n (%) 5 6 ≥6	 307 (90%) 33 (10) 3 (<1)

Source: Brown RS, et al. J Hepatol. 2020;72:441-8.

Glecaprevir-Pibrentasvir in GT 1-6 & Compensated Cirrhosis
EXPEDITION-8: Baseline Characteristics

Baseline Characteristic	Glecaprevir-Pibrentasvir (n = 343)
Median HCV RNA level, log_{10} IU/mL (range)	6.3 (5.7-6.6)
HCV Genotypes, n (%)	
1 (all)	231 (67)
1a	95 (28)
1b	136 (40)
2	26 (8)
3	63 (18)
4	13 (4)
5	1 (<1)
6	9 (13)
Baseline polymorphisms	
None	218/335 (65)
NS3 only	4/335 (1)
NS5A only	111/335 (33)
NS3 and NS5A	2/335 (<1)

Source: Brown RS, et al. J Hepatol. 2020;72:441-8.

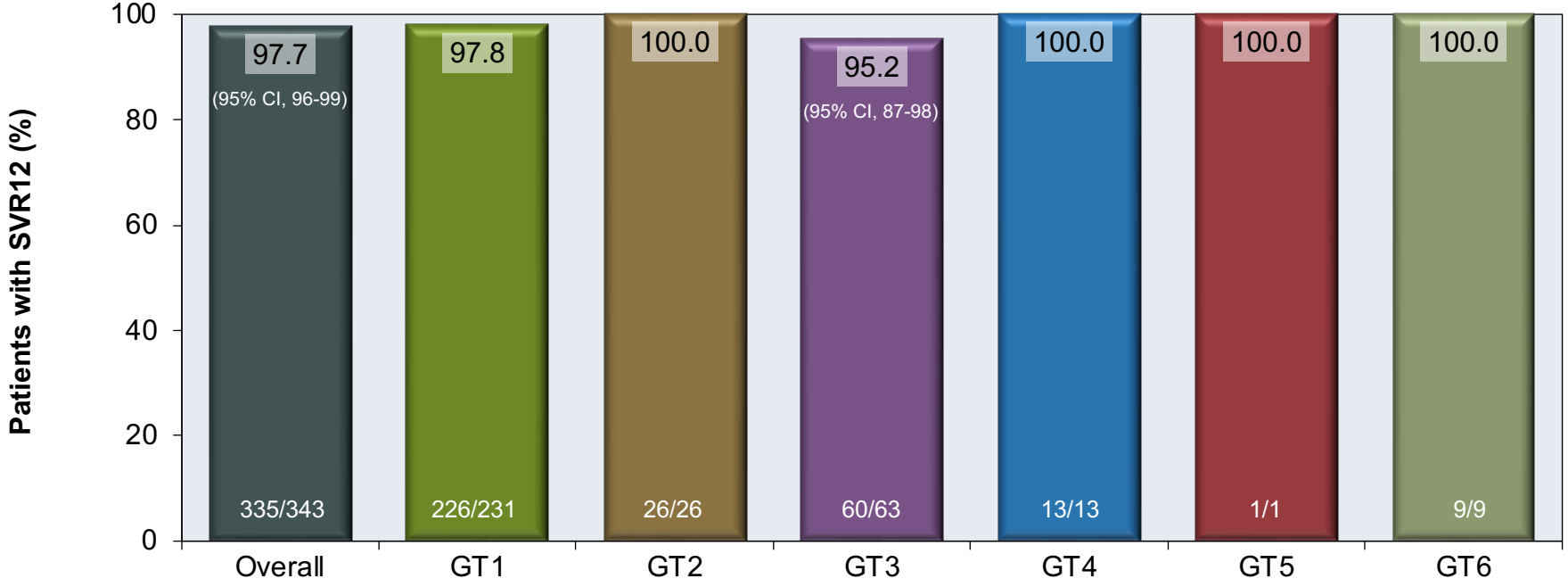
Glecaprevir-Pibrentasvir in GT 1-6 & Compensated Cirrhosis
EXPEDITION-8: Method to Determine Cirrhosis Eligibility

Method Used to Determine Cirrhosis Eligibility	Patients (%) (n = 343)
Histology (METAVIR F4 or equivalent)	32 (9.3)
FibroScan ≥14.6 kPa (no histology data available)	285 (83.1)
FibroTest ≥0.75 and APRI >2 (no histology or FibroScan data available)	26 (7.6)

Source: Brown RS, et al. J Hepatol. 2020;72:441-8.

Glecaprevir-Pibrentasvir in GT 1-6 & Compensated Cirrhosis
EXPEDITION-8: Results (Intent-to-Treat)

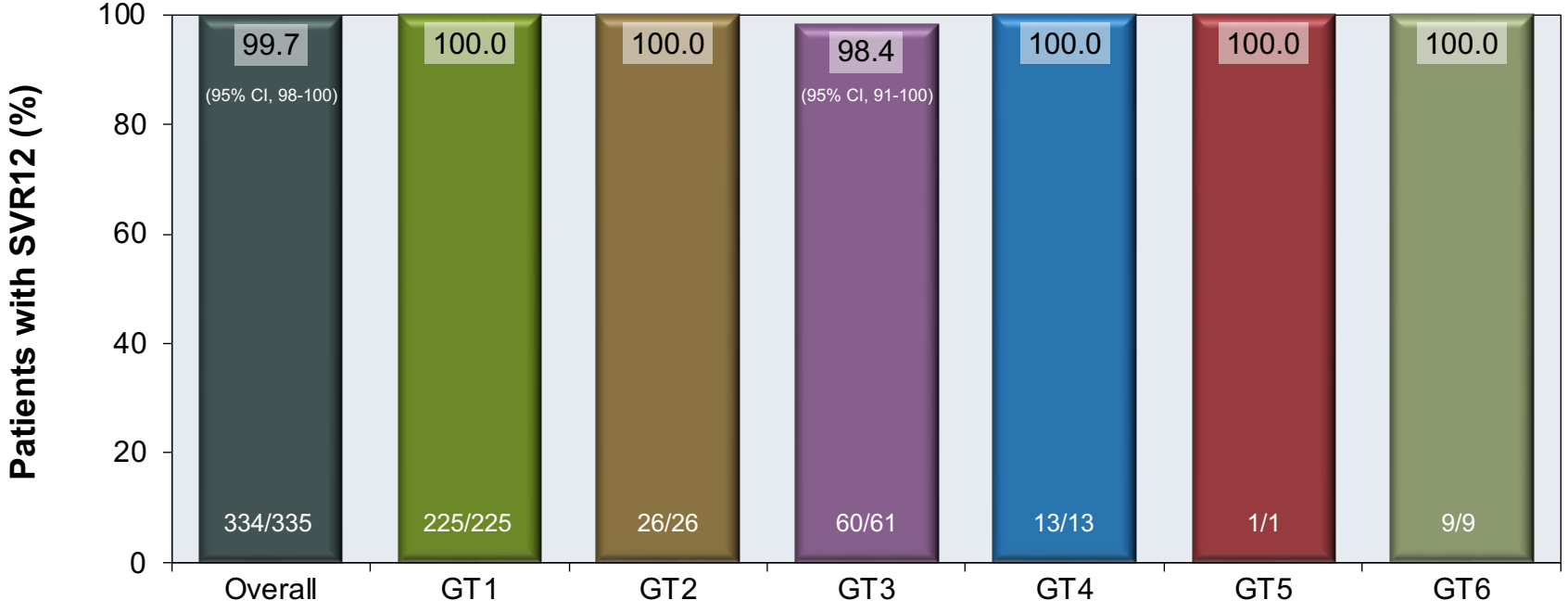
Sustained Virologic Response Rates (SVR): ITT Analysis



Source: Brown RS, et al. J Hepatol. 2020;72:441-8.

Glecaprevir-Pibrentasvir in GT 1-6 & Compensated Cirrhosis
EXPEDITION-8: Results (Per Protocol Analysis)

Sustained Virologic Response Rates (SVR): Per Protocol Analysis



Source: Brown RS, et al. J Hepatol. 2020;72:441-8.

Glecaprevir-Pibrentasvir in GT 1-6 & Compensated Cirrhosis
EXPEDITION-8: Adverse Events

Adverse Event (AE), n (%)	Glecaprevir-Pibrentasvir (n = 343)
Any serious adverse event	6 (2)
Any drug-related serious adverse event	0
Adverse event leading to treatment discontinuation	0
AEs occurring in ≥5% of patients Fatigue Pruritus Headache Nausea	 30 (9) 29 (8) 28 (8) 19 (6)
Alanine aminotransferase >5x ULN, grade ≥3	1/342 (<1)
Total bilirubin >3x ULN, grade ≥3	0/342 (0)
Hemoglobin <8 g/dL, grade ≥3	0/342 (0)
Neutrophil count (<1.0 x 10^9/L)	2/342 (≤1)

Source: Brown RS, et al. J Hepatol. 2020;72:441-8.

Glecaprevir-Pibrentasvir in GT 1-6 & Compensated Cirrhosis
EXPEDITION-8: Conclusions

Conclusions: “Eight-week glecaprevir/pibrentasvir was well tolerated and led to a similarly high SVR12 rate as the 12-week regimen in treatment-naïve patients with chronic HCV GT1-6 infection and compensated cirrhosis.”

Source: Brown RS, et al. J Hepatol. 2020;72:441-8.

Acknowledgments

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