Glecaprevir-Pibrentasvir in GT 1-6 with Renal Disease
EXPEDITION-5

Source: Lawitz E, et al. Liver Int. 2020;40:1032-41.

Glecaprevir-Pibrentasvir in Genotype 1-6 with Renal Disease
EXPEDITION-5: 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 8, 12, or 16 weeks in treatment-naïve and treatment-experienced participants with chronic HCV infection with advanced renal insufficiency
- **Setting:** United States, Canada, Europe, and Asia
- **Key Eligibility Criteria**
  - Age ≥18 years
  - Chronic HCV GT 1, 2, 3, 4, 5, or 6
  - Estimated eGFR <45 mL/min/1.73 m^2 (Stage 3b, 4 or 5 CKD)
  - HCV RNA ≥1,000 IU/mL at screening
  - Naïve or treated with peginterferon +/- ribavirin (PR) or PR +/- sofosbuvir
  - Without cirrhosis or with compensated cirrhosis
  - HIV or chronic HBV coinfection excluded
- **Primary End Point**: SVR12

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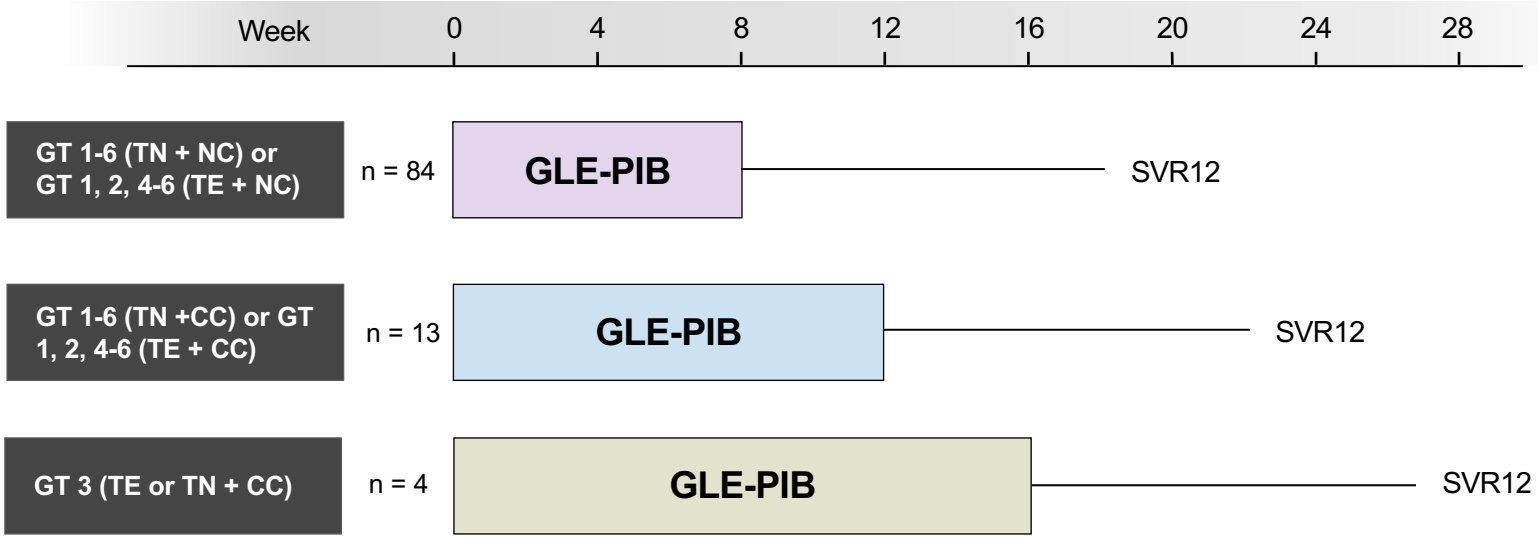
Glecaprevir-Pibrentasvir in Genotype 1-6 with Renal Disease
EXPEDITION-5: Study Design



Abbreviations: GLE-PIB = glecaprevir-pibrentasvir; GT, genotype; TN = treatment-naïve; TE = treatment-experienced; NC = non-cirrhotic; CC = compensated cirrhosis

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

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Glecaprevir-Pibrentasvir in Genotype 1-6 with Renal Disease
EXPEDITION-5: Baseline Characteristics

	GLE-PIB 8 weeks (n = 84)	**GLE-PIB** 12 weeks (n = 13)	**GLE-PIB** 16 weeks (n = 4)
Median age, (range) years	59 (32-84)	58 (49-87)	62 (54-70)
Male sex, n (%)	51 (61)	7 (54)	2 (50)
Race, n (%)			
White	62 (74)	8 (62)	4 (100)
Black	11 (13)	3 (23)	0
Asian	11 (13)	2 (15)	0
Latinx	16 (19)	1 (8)	1 (25)
BMI, median (range), kg/m^2	24.9 (16.8-53.5)	28.7 (17.1-41.1)	24.3 (17.7-26.8)
HCV RNA ≥1 million IU/ml, n (%)	34 (40)	5 (38)	3 (75)
HCV genotype, n (%)			
GT 1	46 (55)	9 (69)	0
GT 2	26 (31)	1 (8)	0
GT 3	9 (11)	2 (15)	4 (100)
GT 4	3 (4)	1 (8)	0

Abbreviations: GLE-PIB = glecaprevir-pibrentasvir; BMI = body mass index; GT, genotype

Source: Lawitz E, et al. Liver Int. 2020;40:1032-41.

Glecaprevir-Pibrentasvir in Genotype 1-6 with Renal Disease
EXPEDITION-5: Baseline Characteristics

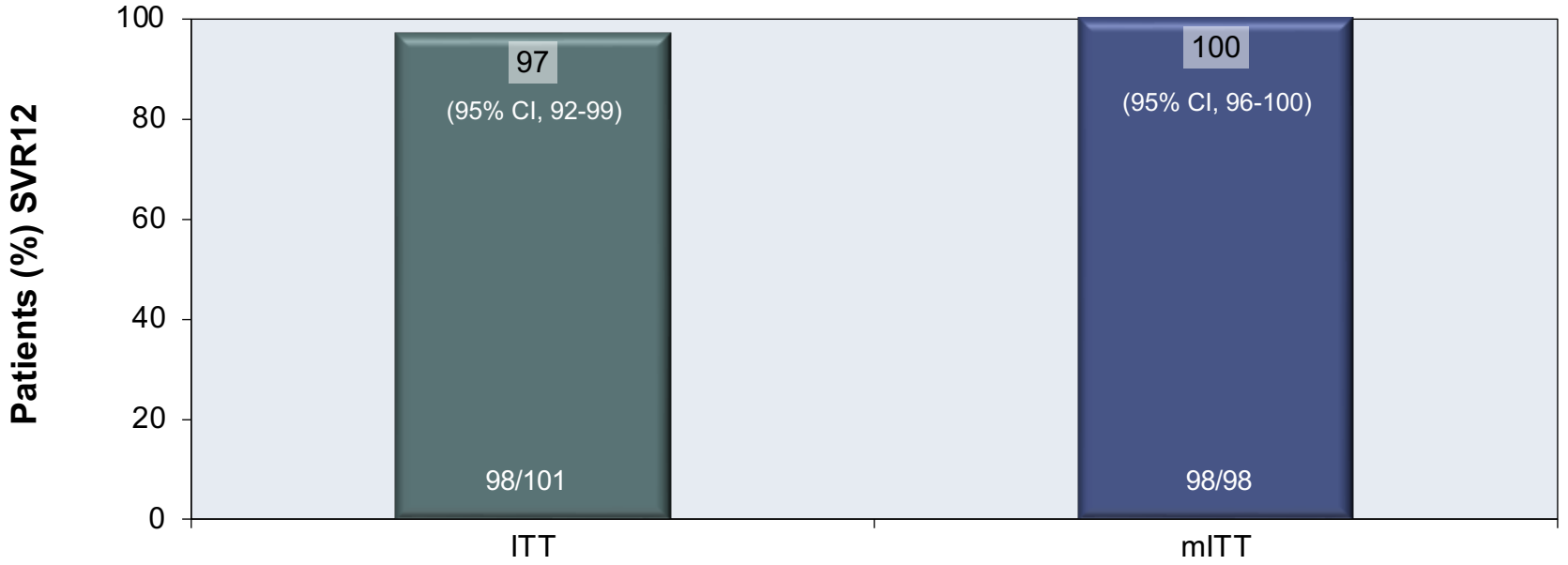
	GLE-PIB 8 weeks (n = 84)	**GLE-PIB** 12 weeks (n = 13)	**GLE-PIB** 16 weeks (n = 4)
Prior treatment experience, n (%)	15 (18)	12 (92)	0
Fibrosis stage, n (%)			
F0-1	61 (73)	0	4 (100)
F2	5 (6)	0	0
F3	16 (19)	0	0
F4	1 (1)	13 (100)	0
Missing	1	0	0
CKD stage, n (%)			
Stage 3b	4 (5)	3 (23)	0
Stage 4	14 (17)	2 (15)	1 (25)
Stage 5	66 (79)	8 (62)	3 (75)
On dialysis, n (%)	66 (79)	8 (62)	3 (75)
Hemodialysis	63 (96)	7 (88)	3 (100)
Peritoneal dialysis	3 (4)	1 (12)	0

Abbreviations: GLE-PIB = glecaprevir-pibrentasvir; CKD = chronic kidney disease

Source: Lawitz E, et al. Liver Int. 2020;40:1032-41.

Glecaprevir-Pibrentasvir in Genotype 1-6 with Renal Disease
EXPEDITION-5: Results

EXPEDITION-5: Overall SVR by Analysis

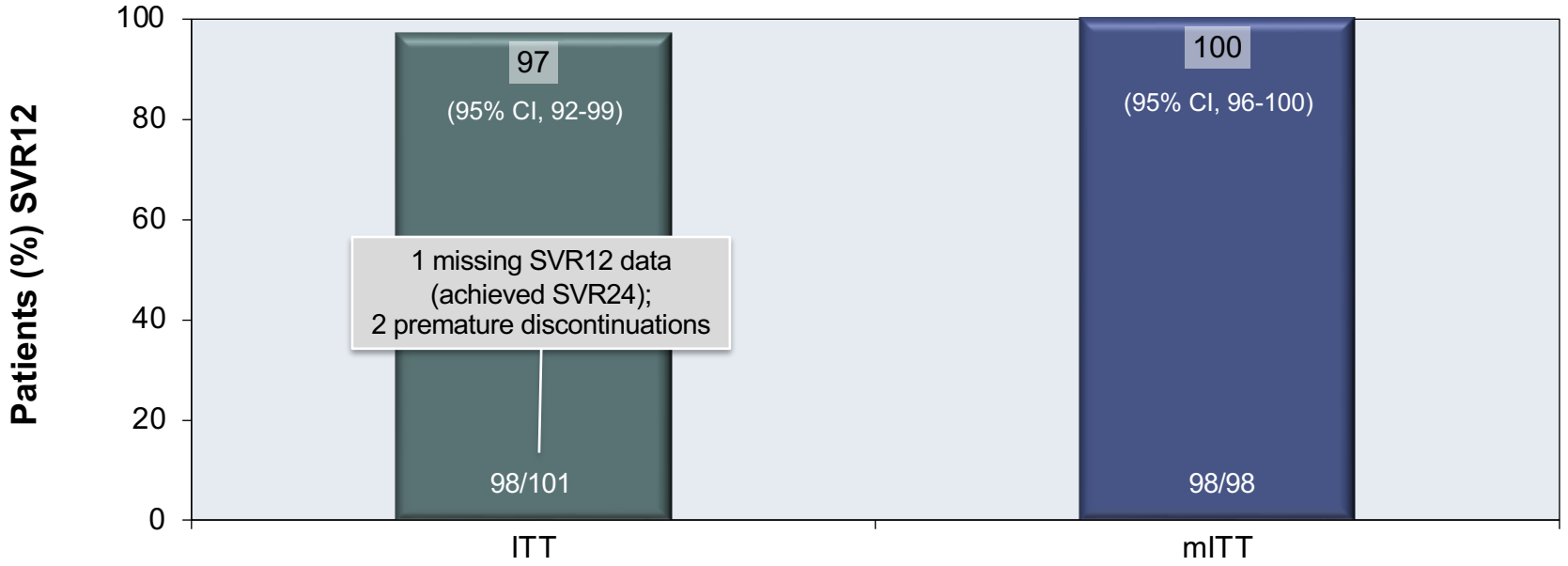


ITT = Intent-to-treat; mITT = modified intent-to-treat

Source: Lawitz E, et al. Liver Int. 2020;40:1032-41.

Glecaprevir-Pibrentasvir in Genotype 1-6 with Renal Disease
EXPEDITION-5: Results

EXPEDITION-5: Overall SVR by Analysis



ITT = Intent-to-treat; mITT = modified intent-to-treat

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Glecaprevir-Pibrentasvir in Genotype 1-6 with Renal Disease
EXPEDITION-5: Adverse Events

Adverse Event (AE), n (%)	Glecaprevir-Pibrentasvir (n = 101)
Serious AE	12 (12)
AE leading to treatment discontinuation	2 (2)
Death	0
AEs occurring in ≥10% of patients	
Pruritus	16 (16)
Hypertension	6 (6)
Generalized pruritus	6 (6)
Bronchitis	6 (6)
Laboratory abnormalities (grade ≥3)	
ALT >5x ULN	0
AST >5x ULN	0
Total bilirubin >3x ULN	0

Abbreviations: AE = adverse event; ALT = alanine aminotransferase; AST = aspartate aminotransferase; ULN = upper limit of normal

Source: Lawitz E, et al. Liver Int. 2020;40:1032-41.

Glecaprevir-Pibrentasvir in Genotype 1-6 with Renal Disease EXPEDITION-5: Conclusions

Conclusion: “Glecaprevir-pibrentasvir treatment yielded high SVR12 rates irrespective of the presence of stage 3b, 4 or 5 CKD. No safety signals were detected.”

Source: Lawitz E, et al. Liver Int. 2020;40:1032-41.

Acknowledgments

Hepatitis C Online is funded by a cooperative agreement from the Centers for Disease Control and Prevention (CDC-RFA- PS21-2105). This project is led by the University of Washington Infectious Diseases Education and Assessment (IDEA) Program.

HEPATITIS B ONLINE

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