

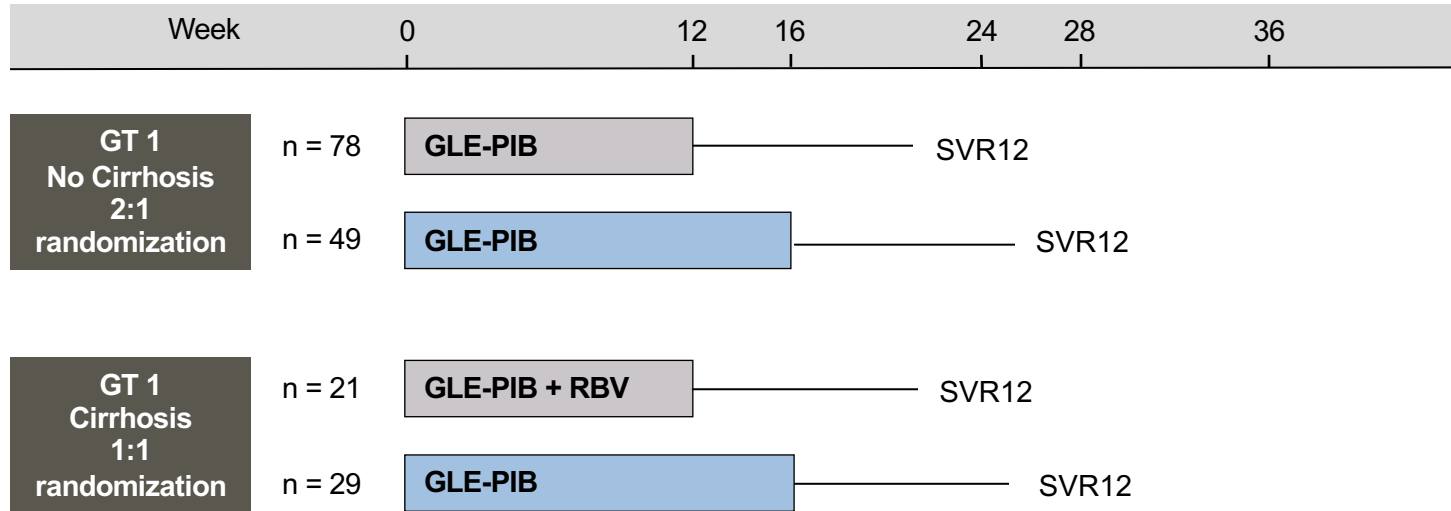
Glecaprevir-Pibrentasvir in Patients with GT 1 and Prior NS5A + Sofosbuvir
HCV-TARGET

Glecaprevir-Pibrentasvir for Retreatment in Patients with GT 1

HCV-TARGET: Study Features

- **Design:** Phase 3b, randomized, open-label study that assessed the safety and efficacy of glecaprevir-pibrentasvir with or without ribavirin for 12 or 16 weeks in patients with genotype 1 and a history of treatment with NS5A inhibitor (ledipasvir, velpatasvir, daclatasvir) and NS5B inhibitor (sofosbuvir).
- **Setting:** 30 centers in the United States (HCV TARGET network)
- **Key Eligibility Criteria**
 - Chronic HCV GT 1
 - Prior treatment: NS5A inhibitor (ledipasvir, velpatasvir, daclatasvir) + sofosbuvir ± ribavirin
 - Compensated cirrhosis permitted
 - Patients with HIV or chronic HBV excluded
- **Primary End Point:** SVR12, by intent-to-treat analysis

Glecaprevir-Pibrentasvir for Retreatment in Patients with GT 1 HCV-TARGET: Study Design



Abbreviations: GLE-PIB = glecaprevir-pibrentasvir; RBV = ribavirin

Drug Dosing

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

Ribavirin (weight-based and divided bid): 1000 mg/day if < 75 kg or 1200 mg/day if ≥ 75 kg.

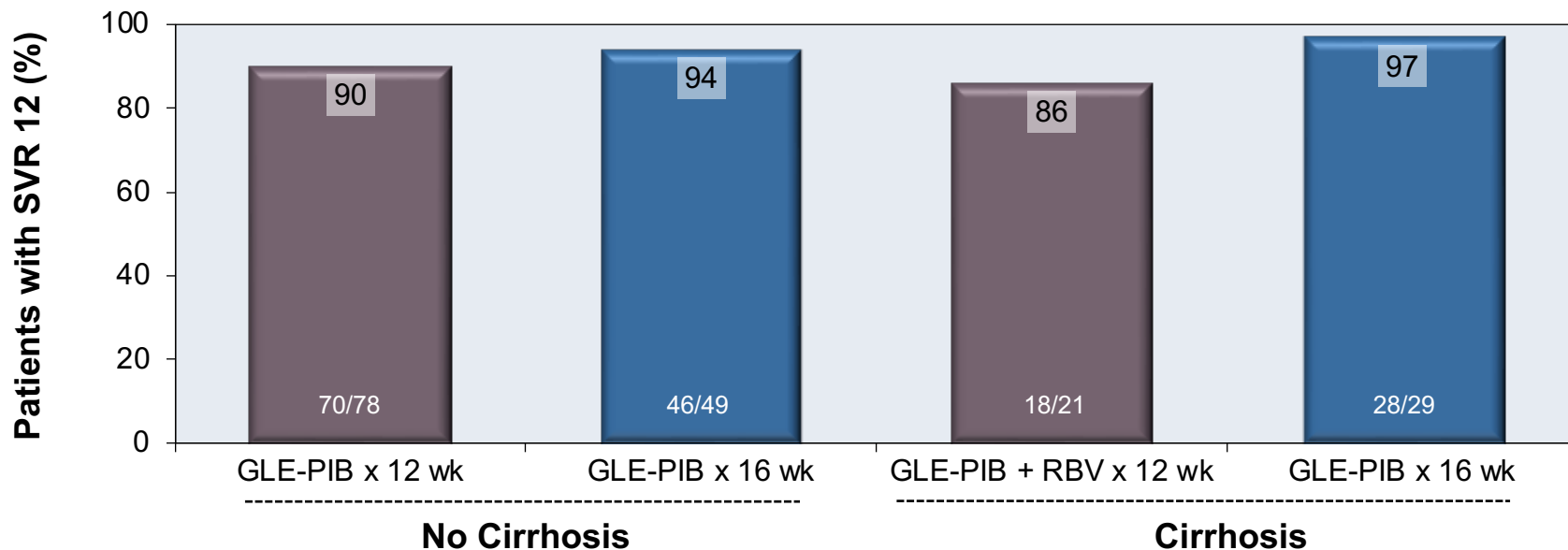
Glecaprevir-Pibrentasvir for Retreatment in Patients with GT 1 HCV-TARGET: Baseline Characteristics

Baseline Characteristic	GT 1 no cirrhosis		GT 1 with cirrhosis	
	GLE-PIB 12 wk (n = 78)	GLE-PIB 16 wk (n = 49)	GLE-PIB + RBV 12 wk (n = 21)	GLE-PIB 16 wk (n = 29)
Male, n (%)	64 (82)	40 (82)	16 (76)	23 (79)
Race, black, n (%)	32 (41)	25 (51)	8 (38)	12 (41)
Age, years, median (range)	62 (40-77)	62 (45-75)	60 (38-70)	64 (42-81)
BMI, kg/m ² mean (range)	28 (19-45)	30 (19-50)	30 (19-53)	27 (23-38)
HCV Genotype 1A, n (%)	60 (77)	39 (80)	17 (81)	26 (90)
HCV RNA, log ₁₀ IU/ml, median (range)	6.4 (1.9-7.7)	6.4 (4.0-7.7)	6.3 (5.1-7.0)	6.4 (3.7-7.1)
Prior DAA treatment, n (%)				
SOF + LDV	74 (95)	45 (92)	21 (100)	26 (90)
SOF + VEL	4 (5)	3 (6)	0	3 (10)
SOF + DCV	0	1 (2)	0	0
Prior PI exposure, n(%)	0	5 (10)	0	3 (10)
History of HCC, n (%)	4 (5)	3 (6)	0	3 (10)
Post-liver transplantation, n (%)	5 (6)	10 (20)	0	0
HIV coinfection, n (%)	5 (6)	2 (4)	1 (5)	1 (3)

Source: Lok A, et al. *Gastroenterology*;2019;157:1506-17.

Glecaprevir-Pibrentasvir for Retreatment in Patients with GT 1 HCV-TARGET: Results

HCV-TARGET: SVR 12* by Cirrhosis Status and Regimen

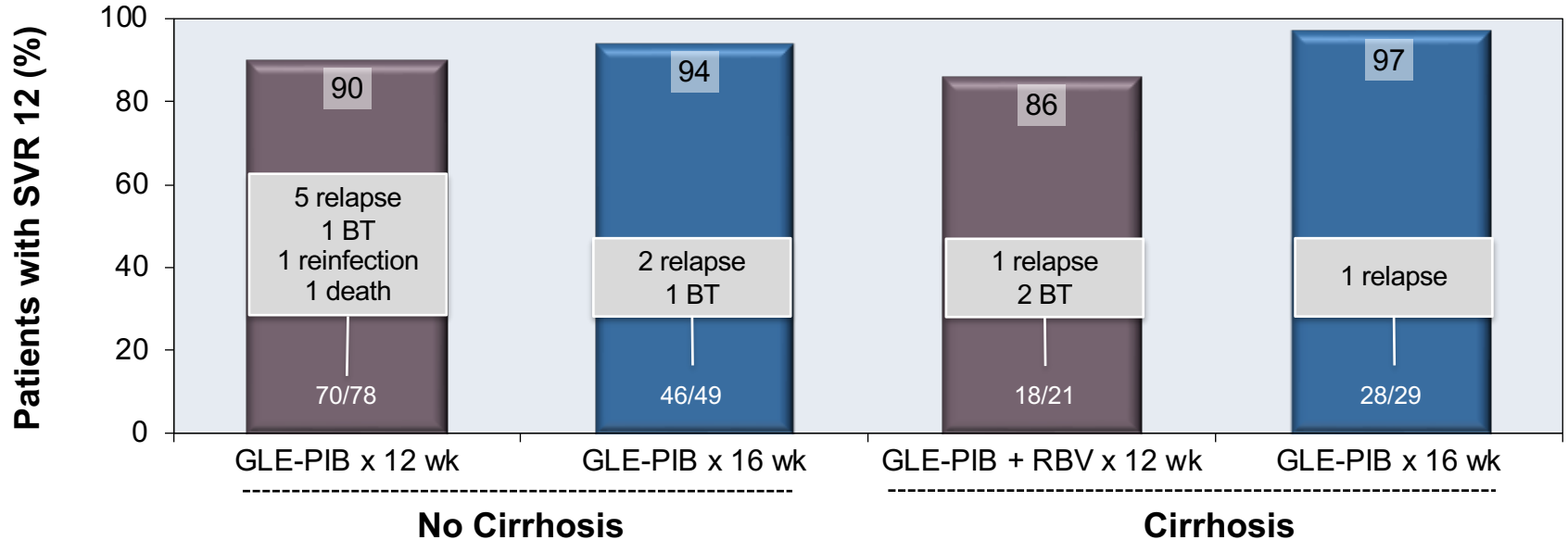


Abbreviations: GLE-PIB = glecaprevir-pibrentasvir; RBV = ribavirin; BT = (virologic) breakthrough

*Primary end point by intention-to-treat analysis

Glecaprevir-Pibrentasvir for Retreatment in Patients with GT 1 HCV-TARGET: Results

HCV-TARGET: SVR 12* by Cirrhosis Status and Regimen



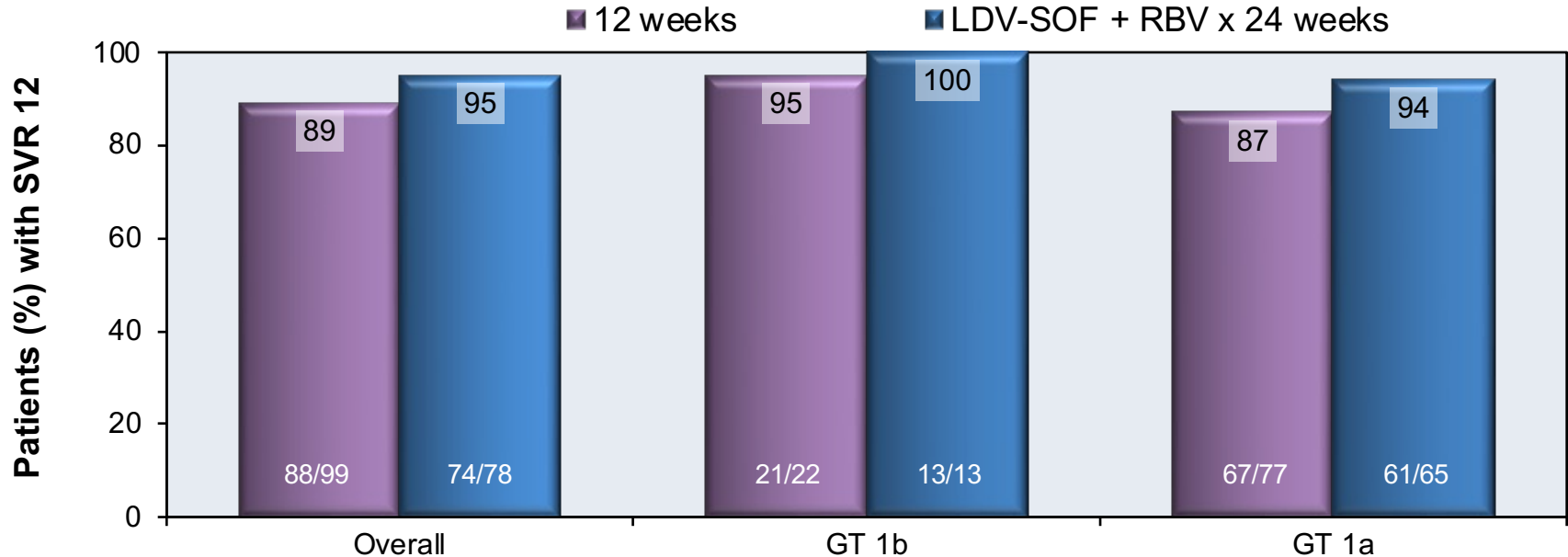
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*Primary end point by intention-to-treat analysis

Glecaprevir-Pibrentasvir for Retreatment in Patients with GT 1 HCV-TARGET: Results

HCV-TARGET: SVR12 Results by Subtype and Duration

Please correct legend – I couldn't do it for blue (16 weeks)



Glecaprevir-Pibrentasvir for Retreatment in Patients with GT 1 HCV-TARGET: Conclusions

Conclusions: “In a randomized study of patients with chronic HCV genotype 1 infection who received previous treatment with sofosbuvir plus an NS5A inhibitor, 16 weeks treatment with G/P produced sustained virologic response 12 weeks after treatment in >90% of patients, including those with compensated cirrhosis.”

Acknowledgments

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