Glecaprevir-Pibrentasvir x 8 or 12 Weeks in GT1 without Cirrhosis
ENDURANCE-1

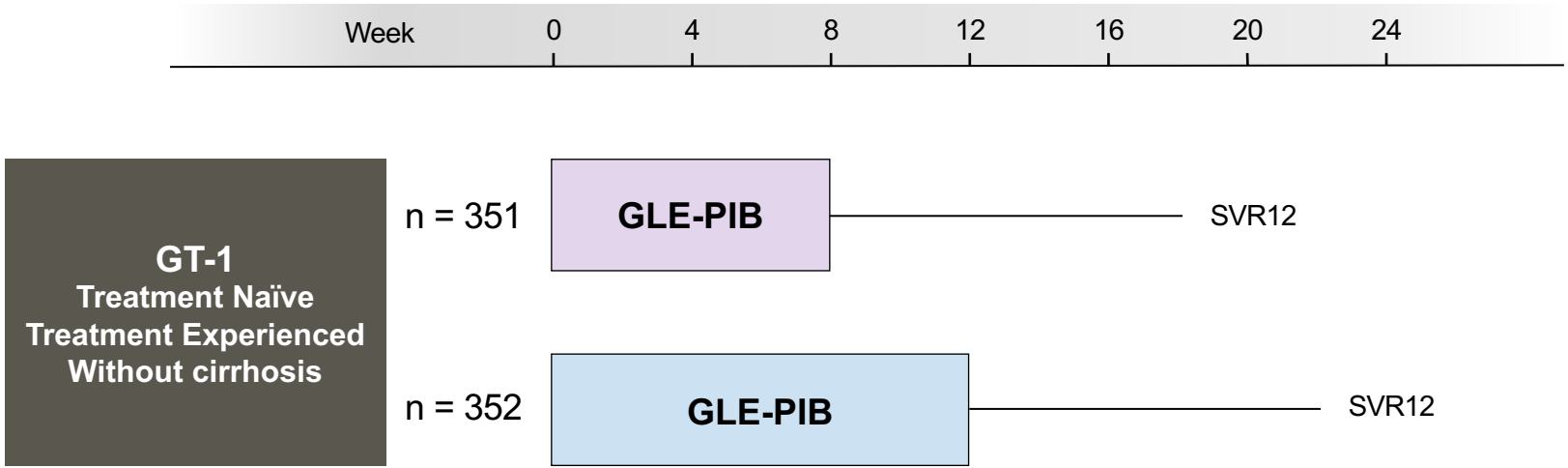
Source: Zeuzem S, et al. N Engl J Med. 2018;378:354-69.

Glecaprevir-Pibrentasvir for 8 or 12 weeks in Non-Cirrhotic GT 1 ENDURANCE-1: Study Features

- **Design:** Randomized, open-labeled, phase 3 trial to evaluate the safety and efficacy of the fixed-dose combination of glecaprevir-pibrentasvir for 8 versus 12 weeks in treatment-naïve or treatment-experienced adults with GT 1 chronic HCV infection without cirrhosis
- **Key Eligibility Criteria**
  - Chronic HCV GT 1
  - Age ≥18
  - HCV RNA ≥1,000 IU/mL at screening
  - Naïve or treated with peginterferon +/- ribavirin (PR) or PR +/- sofosbuvir
  - Absence of cirrhosis
  - HIV coinfection allowed; chronic HBV coinfection excluded
- **Primary End Point:** SVR12

Source: Zeuzem S, et al. N Engl J Med. 2018;378:354-69.

Glecaprevir-Pibrentasvir for 8 or 12 weeks in Non-Cirrhotic GT 1 ENDURANCE-1: Study Design



Abbreviations: GLE-PIB= Glecaprevir-pibrentasvir

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

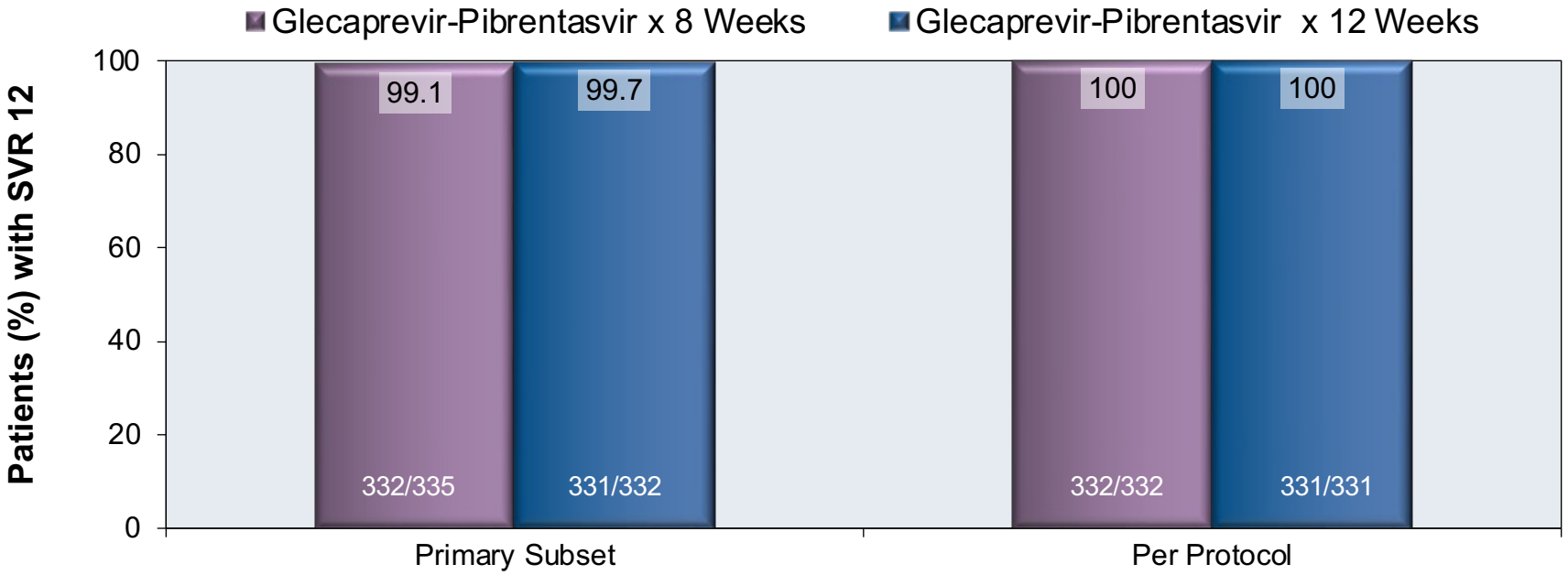
Source: Zeuzem S, et al. N Engl J Med. 2018;378:354-69.

Glecaprevir-Pibrentasvir for 8 or 12 weeks in Non-Cirrhotic GT 1 ENDURANCE-1: Baseline Characteristics

Baseline Characteristics	GLE-PIB 8 weeks (n = 351)	GLE-PIB 12 weeks (n = 352)
Median age, (range), years	53 (19-84)	52 (21-77)
Male, n (%)	167 (48)	176 (50)
Black race, n (%)	14 (4)	13 (4)
HCV subtype 1a, n (%)	151 (43)	144 (41)
Body mass index, median kg/m^2 (range)	25 (18-41)	25 (18-54)
Median HCV RNA, log$_{10}$ IU/mL (range)	6.1 (1.2-7.6)	6.1 (3.3-7.4)
Non-CC IL28B genotype, n (%)	249 (71)	266 (76)
Fibrosis Stage, n (%)		
F0 or F1	296/348 (85)	298/351 (85)
F2	22/348 (6)	24/351 (7)
F3	30/348 (9)	29/351 (8)
Injection drug use, n (%)	98 (28)	98 (28)
HIV coinfection n (%)	15 (4)	18 (5)

Source: Zeuzem S, et al. N Engl J Med. 2018;378:354-69.

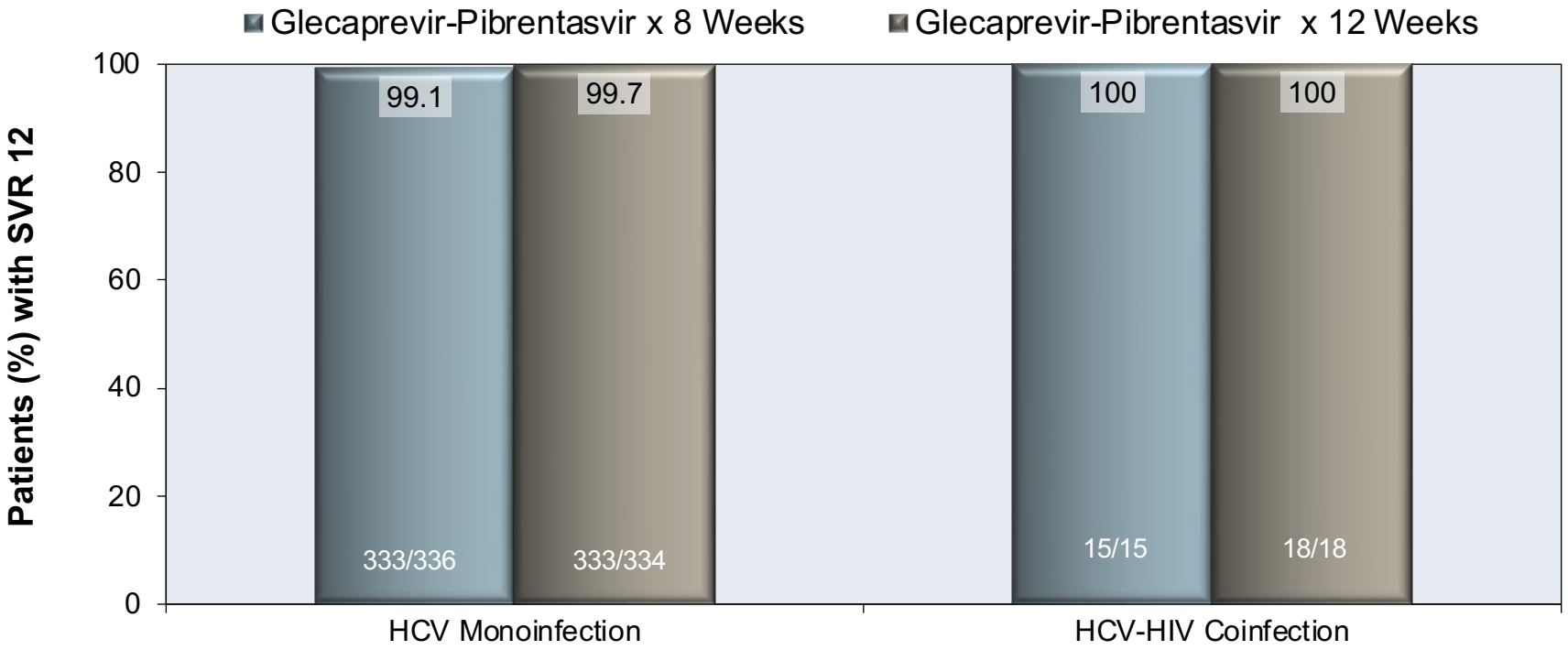
Glecaprevir-Pibrentasvir for 8 or 12 weeks in Non-Cirrhotic GT 1 ENDURANCE-1: Baseline Characteristics



Primary Subset: excludes patients with HIV or previous treatment with sofosbuvir
Per-Protocol: excludes patients in primary subset who (1) prematurely discontinued treatment or had virologic failure during treatment before week 8, or (2) patients without virologic failure who had no HCV RNA value in the SVR12 assessment window

Source: Zeuzem S, et al. N Engl J Med. 2018;378:354-69.

Glecaprevir-Pibrentasvir for 8 or 12 weeks in Non-Cirrhotic GT 1 ENDURANCE-1: Baseline Characteristics



Source: Zeuzem S, et al. N Engl J Med. 2018;378:354-69.

Glecaprevir-Pibrentasvir for 8 or 12 weeks in Non-Cirrhotic GT 1 *ENDURANCE-1: Conclusions

Conclusion: “Once-daily treatment with glecaprevir–pibrentasvir for either 8 weeks or 12 weeks achieved high rates of sustained virologic response among patients with HCV genotype 1 or 3 infection who did not have cirrhosis.”

***Note**: ENDURANCE-1 was published in conjunction with ENDURANCE-3

Source: Zeuzem S, et al. N Engl J Med. 2018;378:354-69.

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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