

Treatment-Naïve and Treatment-Experienced

Glecaprevir and Pibrentasvir in HCV GT 1-6 without Cirrhosis SURVEYOR-I and SURVEYOR-II

Source: Kwo PY, et al. J Hepatol 2017;67:263-71.

Glecaprevir and Pibrentasvir in HCV GT 1-6 without Cirrhosis SURVEYOR-I and SURVEYOR-II: Study Features

SURVEYOR-I and SURVEYOR-II

- **Design:** Open-label single-arm phase 2, multicenter trial to evaluate the safety and efficacy of various doses of glecaprevir and pibrentasvir, with or without ribavirin, for 8 or 12 weeks in treatment-naïve and treatment-experienced, non-cirrhotic patients with chronic HCV GT 1, 2, 3, 4, 5, or 6
- **Setting:** 80 sites in U.S., Canada, Europe, Australia, and New Zealand
- **Key Eligibility Criteria**
 - SURVEYOR I = Chronic HCV GT 1, 4, 5, or 6
 - SURVEYOR 2 = Chronic HCV GT 2 or 3
 - Age 18-70 years
 - HCV RNA >10,000 IU/mL at screening
 - Naïve or treated with peginterferon plus ribavirin
 - Absence of cirrhosis
- **Primary End-Point:** SVR12

Glecaprevir and Pibrentasvir in HCV GT 1-6 without Cirrhosis SURVEYOR-I and SURVEYOR-II: Study Design (Part 1)

Week

0

12

24

Part 1: Dose Ranging in Treatment-Naïve and Treatment-Experienced

GT 1: TN/TE	n = 40	GLE 200 mg + PIB 120 mg	SVR12
GT 1: TN/TE	n = 39	GLE 200 mg + PIB 40 mg	SVR12
GT 2: TN/TE	n = 25	GLE 300 mg + PIB 120 mg	SVR12
GT 2: TN/TE	n = 24	GLE 200 mg + PIB 120 mg + RBV	SVR12
GT 2: TN/TE	n = 25	GLE 300 mg + PIB 120 mg	SVR12
GT 3: TN/TE	n = 30	GLE 200 mg + PIB 120 mg	SVR12
GT 3: TN/TE	n = 30	GLE 200 mg + PIB 120 mg + RBV	SVR12
GT 3: TN/TE	n = 31	GLE 200 mg + PIB 40 mg	SVR12
GT 3: TN/TE	n = 30	GLE 200 mg + PIB 40 mg	SVR12

Abbreviations: TN = Treatment Naïve; TE = Treatment Experienced; GLE = glecaprevir; PIB = pibrentasvir; RBV = ribavirin

Glecaprevir and Pibrentasvir in HCV GT 1-6 without Cirrhosis SURVEYOR-I and SURVEYOR-II: Study Design (Part 2)

Week

0

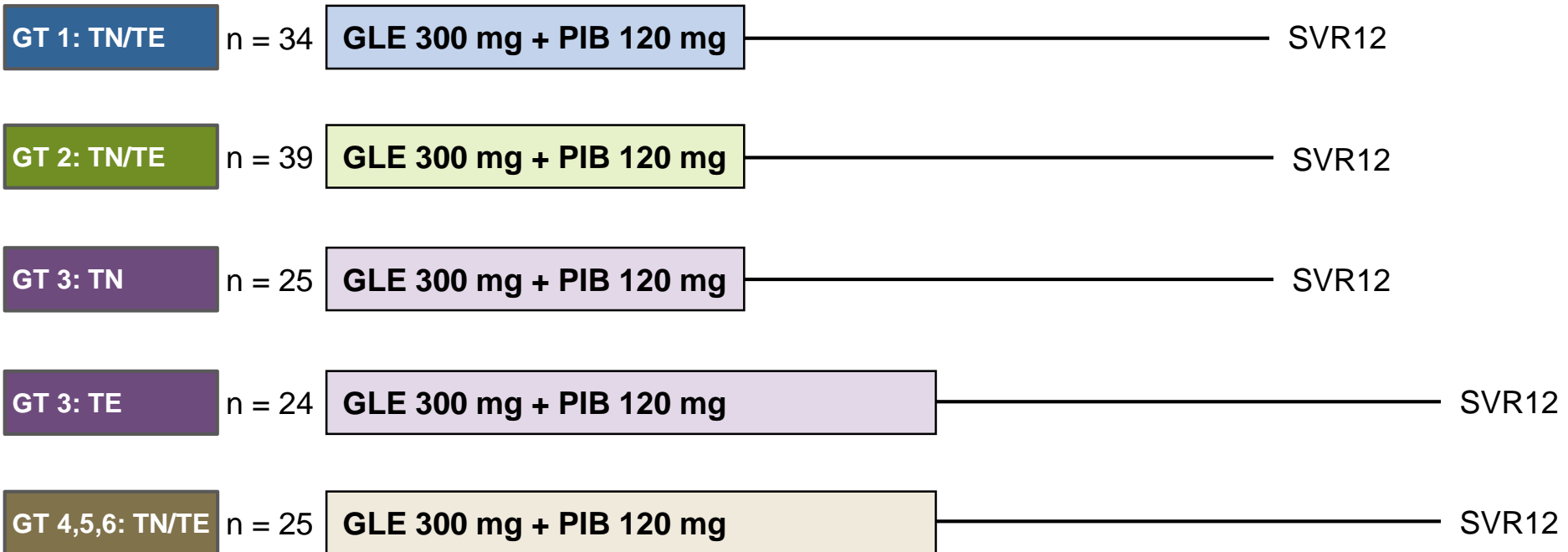
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Part 2: Optimized Dose Combination for 8 Weeks in Treatment-Naïve and Treatment-Experienced



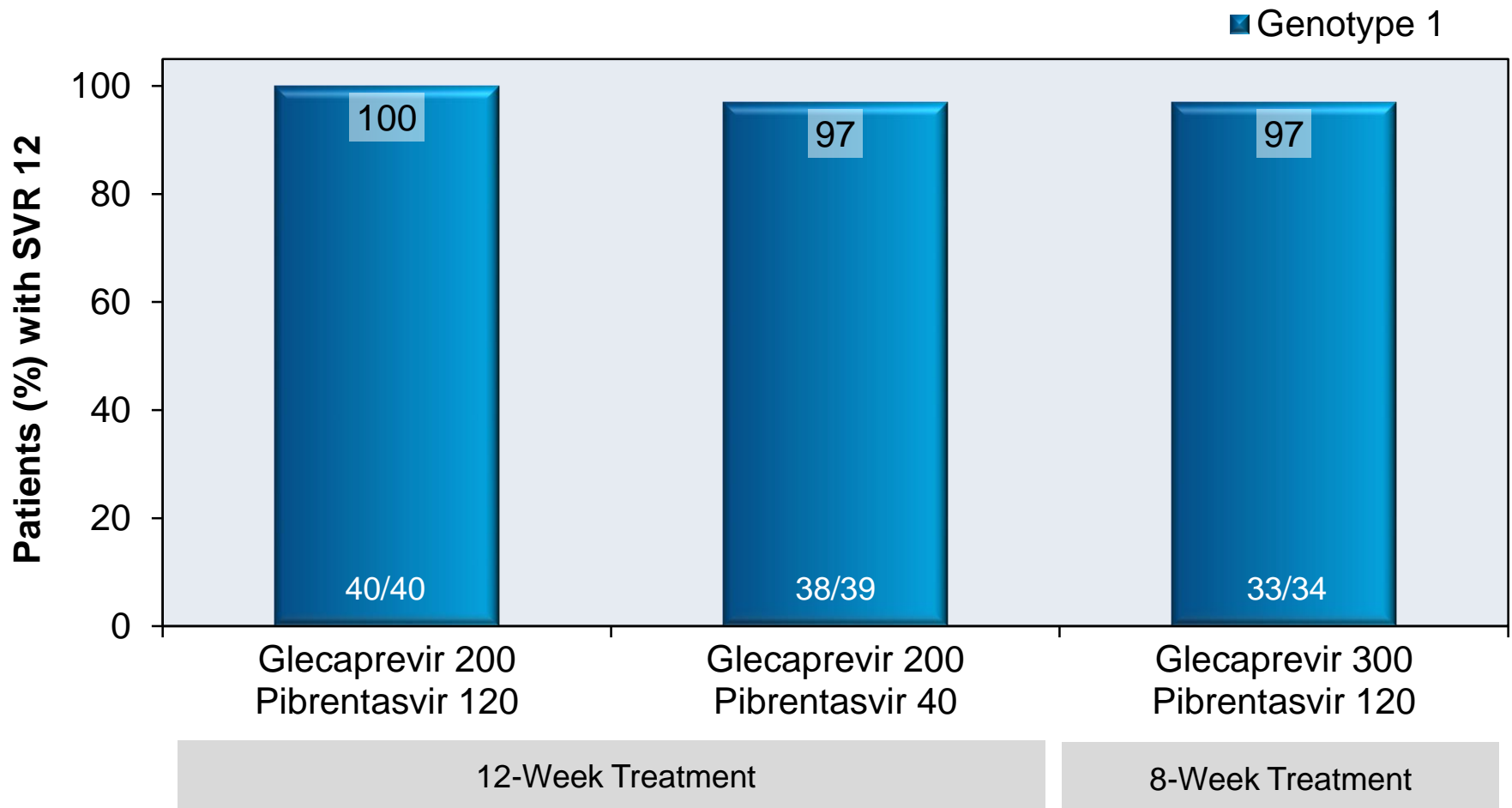
Abbreviations: TN = Treatment Naïve; TE = Treatment Experienced; GLE = glecaprevir; PIB = pibrentasvir

Glecaprevir and Pibrentasvir in HCV GT 1-6 without Cirrhosis SURVEYOR-I and SURVEYOR-II: Baseline Characteristics

Prevalence of Baseline Amino Acid Polymorphisms			
Genotype	Amino Acid Polymorphisms, n/N %		
	NS3 Only	NS5A Only	NS3 + NS5A
1a	40/87 (46)	9/87 (10)	12/87 (14)
1b	10/24 (42)	4/24 (17)	4/24 (17)
2	3/124 (2)	79/124 (64)	11/124 (9)
3	22/174 (13)	33/174 (19)	7/174 (4)
4	1/22 (5)	7/22 (32)	0/22 (0)
5	0/1 (0)	0/1 (0)	0/1 (0)
6	2/11 (18)	4/11 (36)	14/11 (9)

Glecaprevir and Pibrentasvir in HCV GT 1-6 without Cirrhosis SURVEYOR-I and SURVEYOR-II: Results

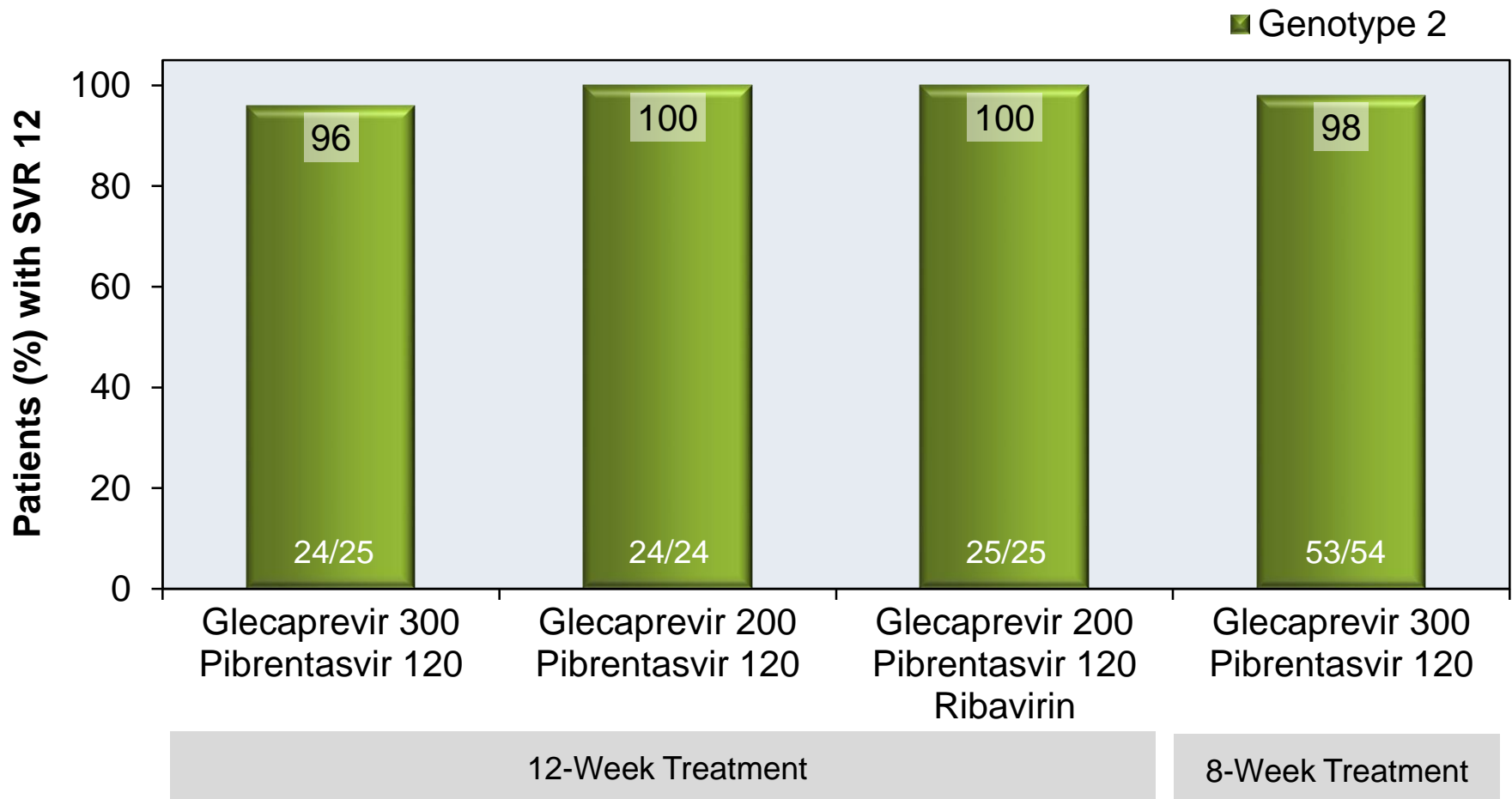
Genotype 1: SVR12 ITT



Source: Kwo PY, et al. J Hepatol 2017;67:263-71.

Glecaprevir and Pibrentasvir in HCV GT 1-6 without Cirrhosis SURVEYOR-I and SURVEYOR-II: Results

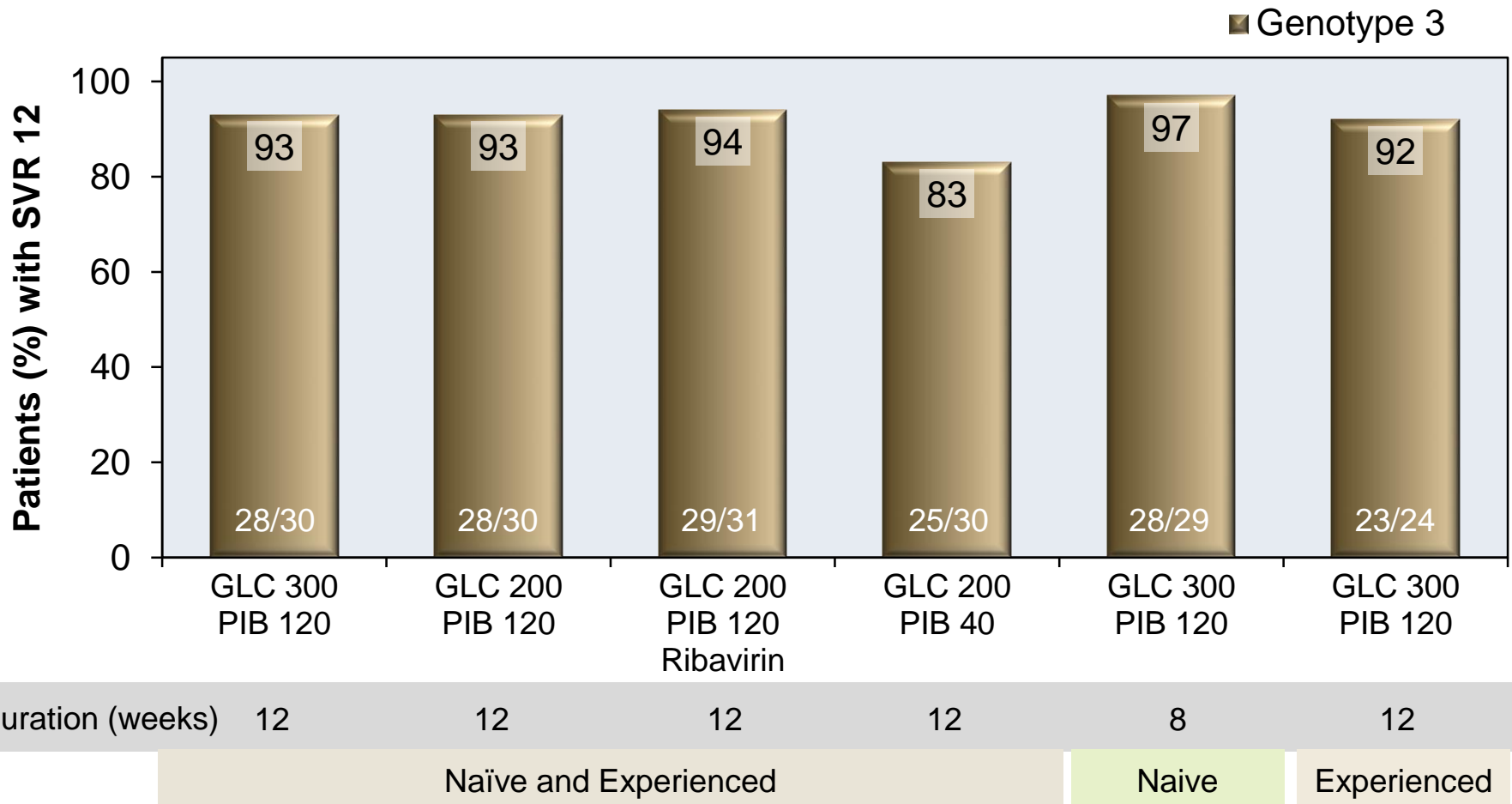
Genotype 2: SVR12 ITT



Source: Kwo PY, et al. J Hepatol 2017;67:263-71.

Glecaprevir and Pibrentasvir in HCV GT 1-6 without Cirrhosis SURVEYOR-I and SURVEYOR-II: Results

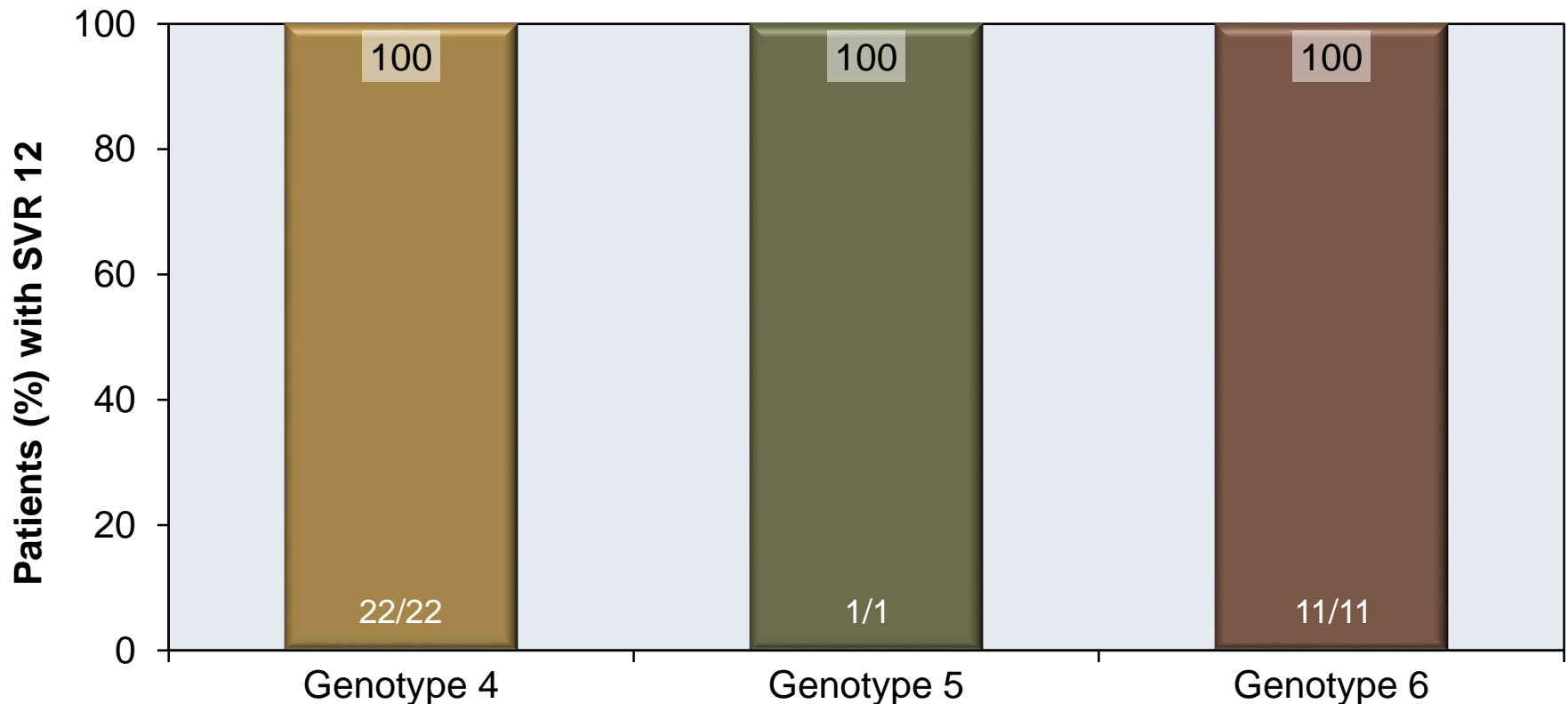
Genotype 3: SVR12 ITT



Source: Kwo PY, et al. J Hepatol 2017;67:263-71.

Glecaprevir and Pibrentasvir in HCV GT 1-6 without Cirrhosis SURVEYOR-I and SURVEYOR-II: Results

Genotype 4, 5, and 6: SVR12 ITT



12-Week Treatment with Glecaprevir 300 mg and Pibrentasvir 120 mg*

Includes 2 patients who received Glecaprevir 200 mg and Pibrentasvir 120 mg)

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Glecaprevir and Pibrentasvir in HCV GT 1-6 without Cirrhosis SURVEYOR-I and SURVEYOR-II: Conclusions

Conclusions: “Glecaprevir plus pibrentasvir was well tolerated and achieved high sustained virologic response rates in HCV genotypes 1-6-infected patients without cirrhosis following 8- or 12-week treatment durations.”