Glecaprevir-Pibrentasvir + Sofosbuvir + Ribavirin for Retreatment in G/P-Experienced

MAGELLAN-3

Source: Wyles D, et al. J Hepatol;2019;70:1019-38.

Glecaprevir-Pibrentasvir + SOF + RBV for Retreatment of HCV GT 1-3 MAGELLAN-3: Study Features

- **Design**: Phase 3b, open-label study that assessed the safety and efficacy of glecaprevir-pibrentasvir plus sofosbuvir with ribavirin for 12 or 16 weeks in patients with a history of failure after glecaprevir-pibrentasvir and GT 1, 2 or 3.
- **Setting:** United States, Australia, Canada, Europe, New Zealand, South Korea, & China
- **Key Eligibility Criteria**
  - Chronic HCV GT 1-3
  - Age 18 years or older or adolescents weighing at least 35 kg
  - HCV RNA >1,000 IU/mL at screening
  - Prior treatment with glecaprevir-pibrentasvir
  - Compensated cirrhosis permitted
  - Patients with HIV or chronic HBV excluded
- **Primary End Point**: SVR12, by intent-to-treat analysis

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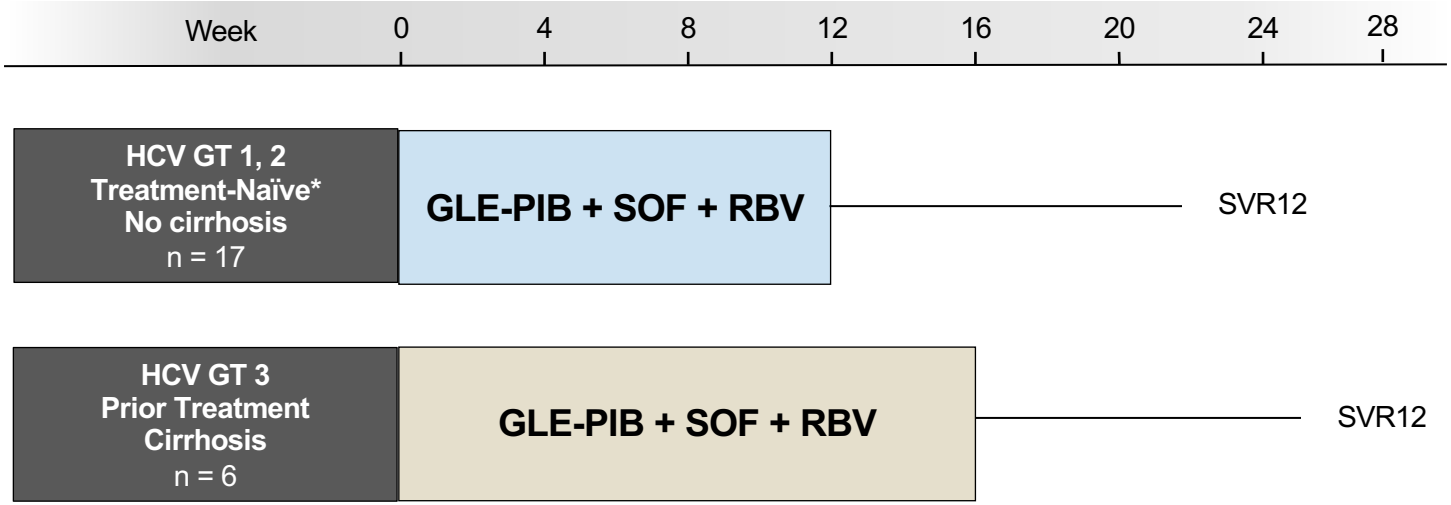
Glecaprevir-Pibrentasvir + SOF + RBV for Retreatment of HCV GT 1-3
MAGELLAN-3: Study Design



Abbreviations: GLE-PIB = glecaprevir-pibrentasvir; SOF = sofosbuvir; RBV = Ribavirin

Naïve* defined as treatment-naïve to NS5A inhibitor or protease inhibitor prior to 1st GLE-PIB treatment

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.

Source: Wyles D, et al. J Hepatol;2019;70:1019-38.

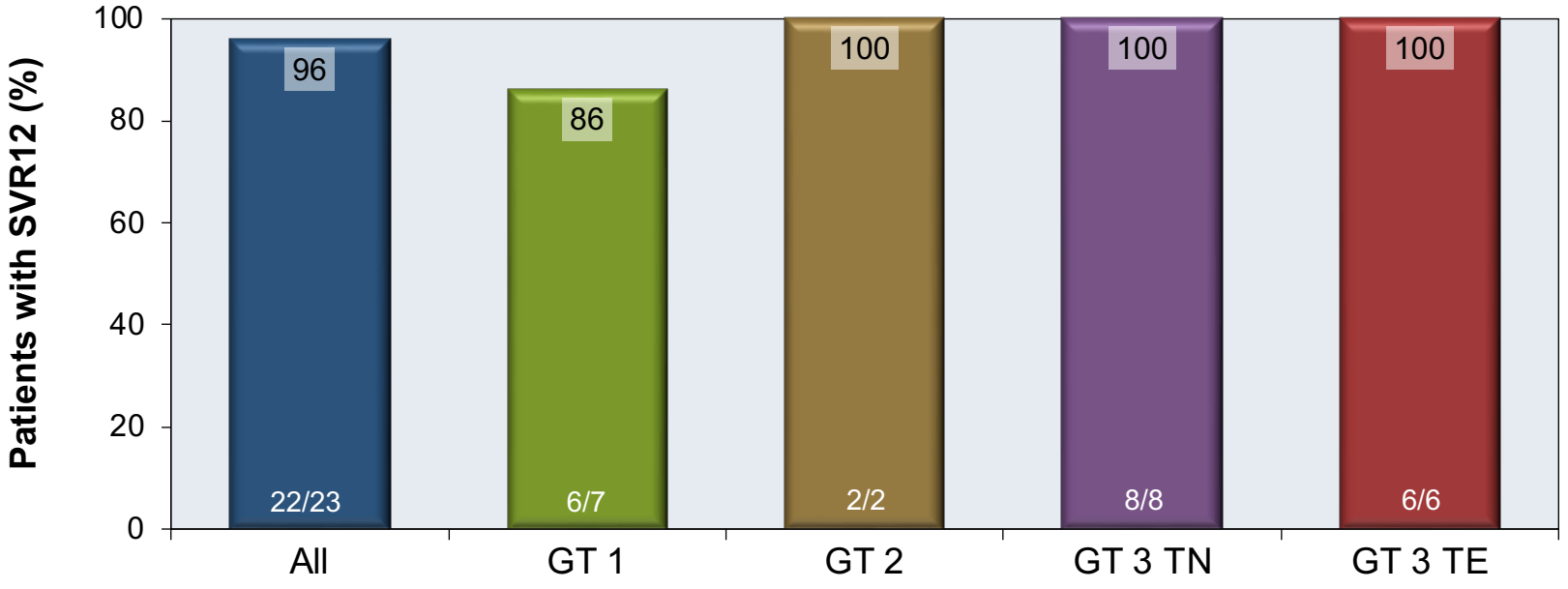
Glecaprevir-Pibrentasvir + SOF + RBV for Retreatment of HCV GT 1-3
MAGELLAN-3: Baseline Characteristics

Baseline Characteristic	12 weeks			16 weeks
	GT 1 (n = 7)	GT 2 (n = 2)	GT 3 naive (n = 8)	GT 3 experienced (n = 6)
Age, median (range)	59 (48-67)	56 (56-56)	50 (38-60)	58 (53-65)
Male, n (%)	4 (57)	1 (50)	7 (88)	6 (100)
Race				
White, n (%)	6 (86)	2 (100)	6 (75)	6 (100)
Asian, n (%)	0	0	2 (25)	0
Black, n (%)	1 (14)	0	0	0
BMI, kg/m^2 mean (range)	34 (20-36)	35 (30-41)	25 (22-30)	27 (22-32)
HCV RNA, $\log_{10}$ IU/ml (median)	6.3 (6.0-6.8)	6.6 (6.6-6.6)	6.2 (3.7-7.4)	6.6 (5.9-7.0)
Cirrhosis, n (%)	4 (57)	0	2 (25)	1 (17)
Presence of baseline RAS, n (%)				
None	0	2 (100)	0	0
NS3 only	0	0	0	0
NS5A only	5 (71)	0	5 (62)	6 (100)
NS3 and NS5A	2 (29)	0	3 (38)	0

Source: Wyles D, et al. J Hepatol;2019;70:1019-38.

Glecaprevir-Pibrentasvir + SOF + RBV for Retreatment of HCV GT 1-3
MAGELLAN-3: Results

MAGELLAN-3: SVR12 Results by Prior Treatment Status and Genotype



Abbreviations: TN = treatment-naïve; TE = treatment-experienced

Source: Wyles D, et al. J Hepatol;2019;70:1019-38.

Glecaprevir-Pibrentasvir + SOF + RBV for Retreatment of HCV GT 1-3
MAGELLAN-3: Conclusions

Conclusions: “Retreatment of glecaprevir-pibrentasvir virologic failures with glecaprevir-pibrentasvir plus sofosbuvir plus ribavirin for 12 or 16 weeks was well-tolerated and high.”

Source: Gane E, et al. Clin Infect Dis. 2019;69:1657-64.

Acknowledgments

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