Glecaprevir-Pibrentasvir in HCV GT 1 & Prior DAA Treatment

MAGELLAN-1 (Part 1)

Source: Poordad F, et al. Hepatology. 2017;66:389-97.

Glecaprevir-Pibrentasvir in HCV GT 1 & Prior DAA Treatment
MAGELLAN-1 (Part 1): Study Features

- **Design**: Randomized, open-label, multicenter, phase 2 trial to evaluate the safety and efficacy of glecaprevir-pibrentasvir with or without ribavirin for 12 weeks in patients with genotype 1 chronic HCV (with or without cirrhosis) who previously experienced virologic failure with direct-acting antiviral (DAA) therapy.
- **Setting**: United States
- **Key Eligibility Criteria**
  - Chronic HCV GT 1
  - HCV RNA >1,000 IU/mL at screening
  - Adults 18-70 years of age
  - Prior failure with DAA-containing therapy (NS5A inhibitor and/or NS3/4A PI +/- NS5B inhibitors)
  - Patients without cirrhosis excluded
  - Patients with HIV or HBV coinfection excluded
- **Primary End Point**: SVR12

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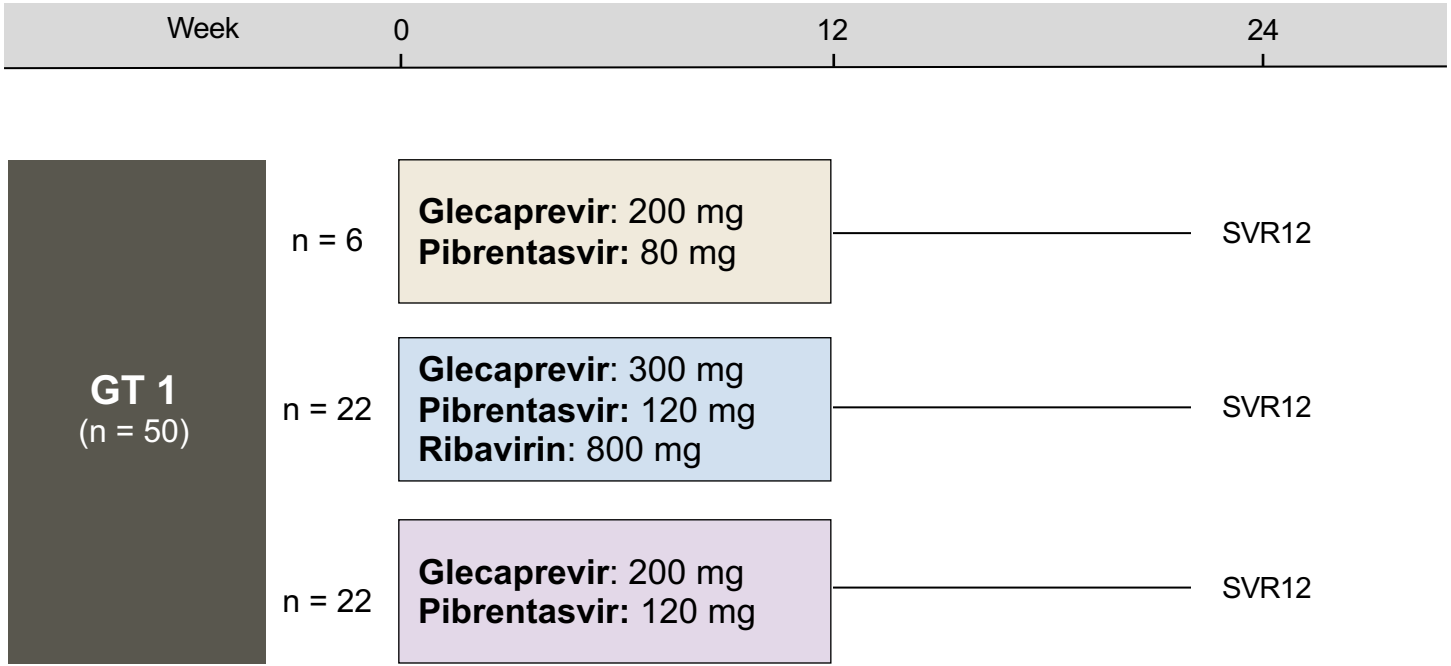
Glecaprevir-Pibrentasvir in HCV GT 1 & Prior DAA Treatment
MAGELLAN-1 (Part 1): Treatment Regimens



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Glecaprevir-Pibrentasvir in HCV GT 1 & Prior DAA Treatment
MAGELLAN-1 (Part 1): Baseline Characteristics

Characteristics	GLE 200 mg + PIB 80 mg (n = 6)	GLE 300 + PIB 120 mg + RBV 800 mg (n = 22)	GLE 200 mg + PIB 120 mg (n = 22)
Age, median years (range)	59 (39-61)	56 (39-64)	59 (46-70)
Male sex, n (%)	3 (50)	20 (91)	18 (82)
Black race, n (%)	2 (33)	5 (23)	10 (45)
BMI, median kg/m^2 (range)	27 (25-37)	28 (22-34)	28 (19-37)
IL28B non-CC genotype, n (%)	4 (67)	16 (73)	19 (86)
HCV RNA level, median $\log_{10}$ IU/mL (range)	6.1 (5.6-6.7)	6.7 (5.0-7.3)	6.6 (5.5-7.2)
Fibrosis stage, n (%) F0-F1 F2 F3	 4 (67) 1 (17) 1 (17)	 17 (77) 0 5 (23)	 11 (50) 6 (27) 5 (23)
HCV subtype 1a, n/N (%)	4 (67)	20 (91)	19 (82)

GLE-PIB = glecaprevir-pibrentasvir; RBV = ribavirin; BMI = body mass index

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Glecaprevir-Pibrentasvir in HCV GT 1 & Prior DAA Treatment
MAGELLAN-1 (Part 1): Baseline Characteristics

Characteristics	GLE 200 + PIB 80 mg (n = 6)	GLE 300 + PIB 120 mg + RBV 800 mg (n = 22)	GLE 200 + PIB 120 mg (n = 22)
Prior DAA class, n (%)			
NS5A-experienced/PI-naïve	0	4 (18)	4 (18)
NS5A-naïve/PI-experienced	3 (50)	11 (50)	11 (50)
NS5A-experienced/PI-experienced	3 (50)	7 (32)	7 (32)
Baseline polymorphisms, n (%)			
Any (NS3 or NS5A)	5 (83)	18 (82)	17 (77)
NS3 only	2 (33)	7 (32)	5 (23)
NS5A only	3 (50)	5 (23)	3 (14)
Both NS3 and NS5A	0	6 (27)	9 (41)

GLE-PIB = glecaprevir-pibrentasvir

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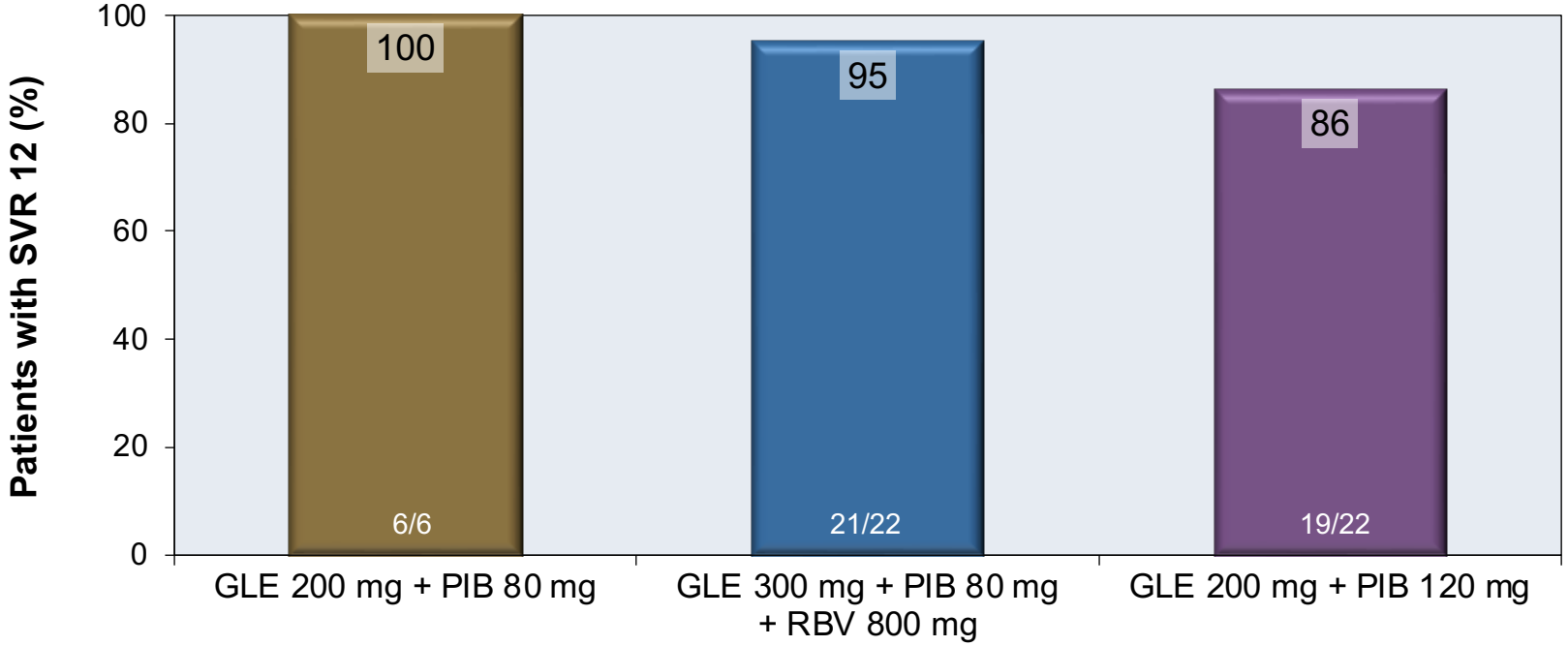
Glecaprevir-Pibrentasvir in HCV GT 1 & Prior DAA Treatment
MAGELLAN-1 (Part 1): Study Design

Intent-to-Treat Analysis



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Glecaprevir-Pibrentasvir in HCV GT 1 & Prior DAA Treatment
MAGELLAN-1 (Part 1): Conclusions

Conclusions: “The combination of glecaprevir and pibrentasvir was highly efficacious and well tolerated in patients with HCV genotype 1 infection and prior failure of DAA-containing therapy; ribavirin coadministration did not improve efficacy.”

Source: Poordad F, et al. Hepatology. 2017;66:389-97.

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.

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