Treatment Experienced

Simeprevir in Treatment –Experienced Genotype 1 ASPIRE Trial

Zeuzem S, et al. Gastroenterol. 2014;146:430-41.

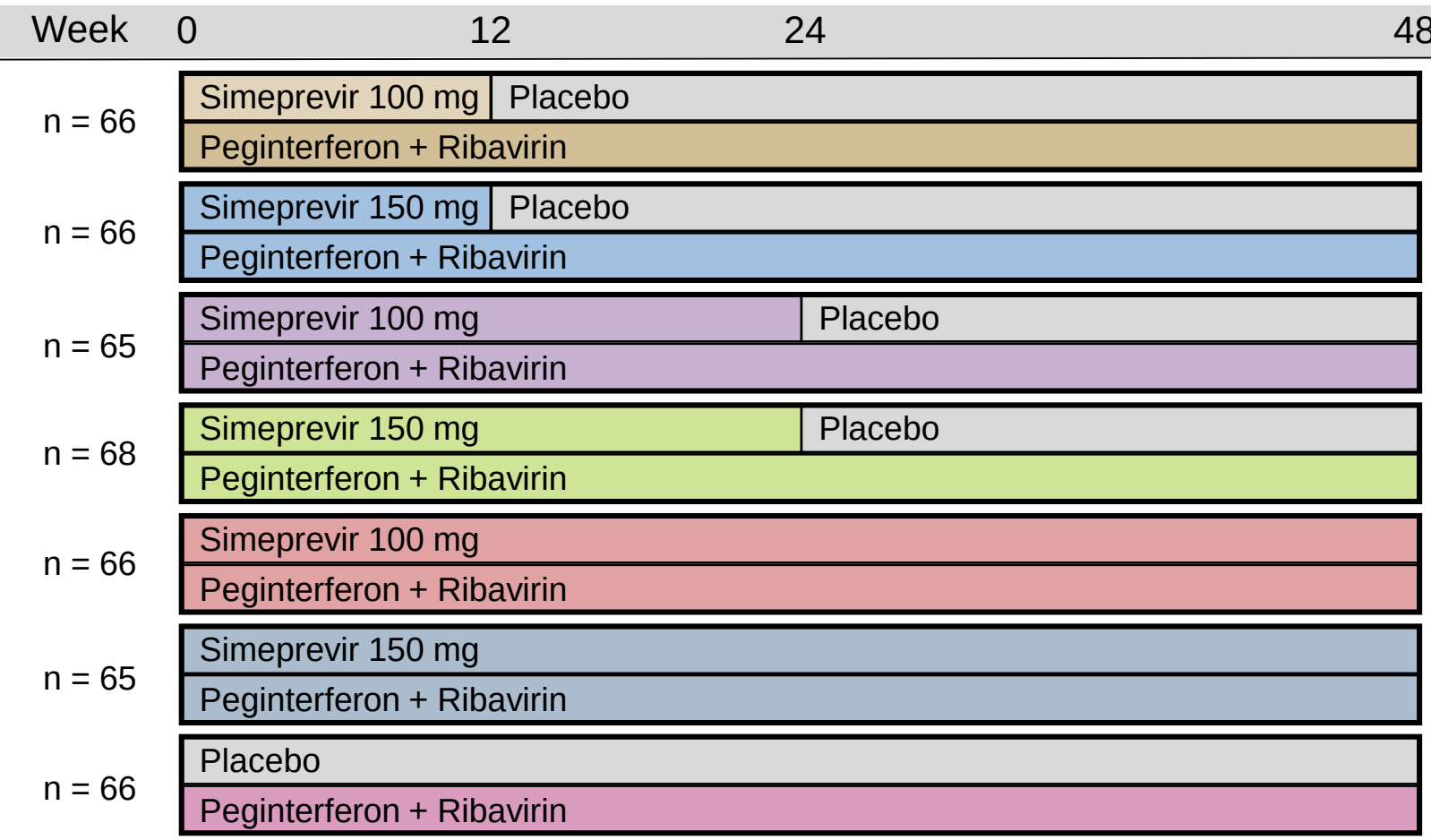
Simeprevir in Treatment Experienced Genotype 1 HCV
ASPIRE Trial: Features

ASPIRE Trial: Study Features

- **Design**: Randomized, double-blind, placebo-controlled, 7 arm, phase 2b trial of PEG and RBV with and without simeprevir in HCV GT1 for prior treatment failures with PEG and RBV
- **Setting**: Europe, North America, Australia, and New Zealand
- **Entry Criteria**
  - Treatment-experienced, chronic HCV GT-1 monoinfection
  - Prior failure with (≥ 12 weeks) of peginterferon-alfa plus ribavirin
  - HCV RNA > 10,000 IU/mL
- **Patient Characteristics**
  - N = 462
  - HCV Genotype: 1a (41%); 1b (58%); other (1%)
  - IL28B Genotype: 82% non-CC
  - Demographics: median age 50; 67% male; 93% white
  - Metavir Fibrosis: F3 = 19%; F4 = 18%
- **Primary end-points**: Efficacy (SVR24)

Source: Zeuzem S, et al. Gastroenterol. 2014;146:430-41.

Simeprevir in Treatment Experienced Genotype 1 HCV
ASPIRE Trial: Design



Drug Dosing: Simeprevir: 100 or 150 mg once daily; Peginterferon alfa-2a (PEG): 180 mcg/week
Ribavirin (RBV) weight-based (in 2 divided doses): 1000 mg if < 75kg or 1200 mg/day if ≥ 75kg

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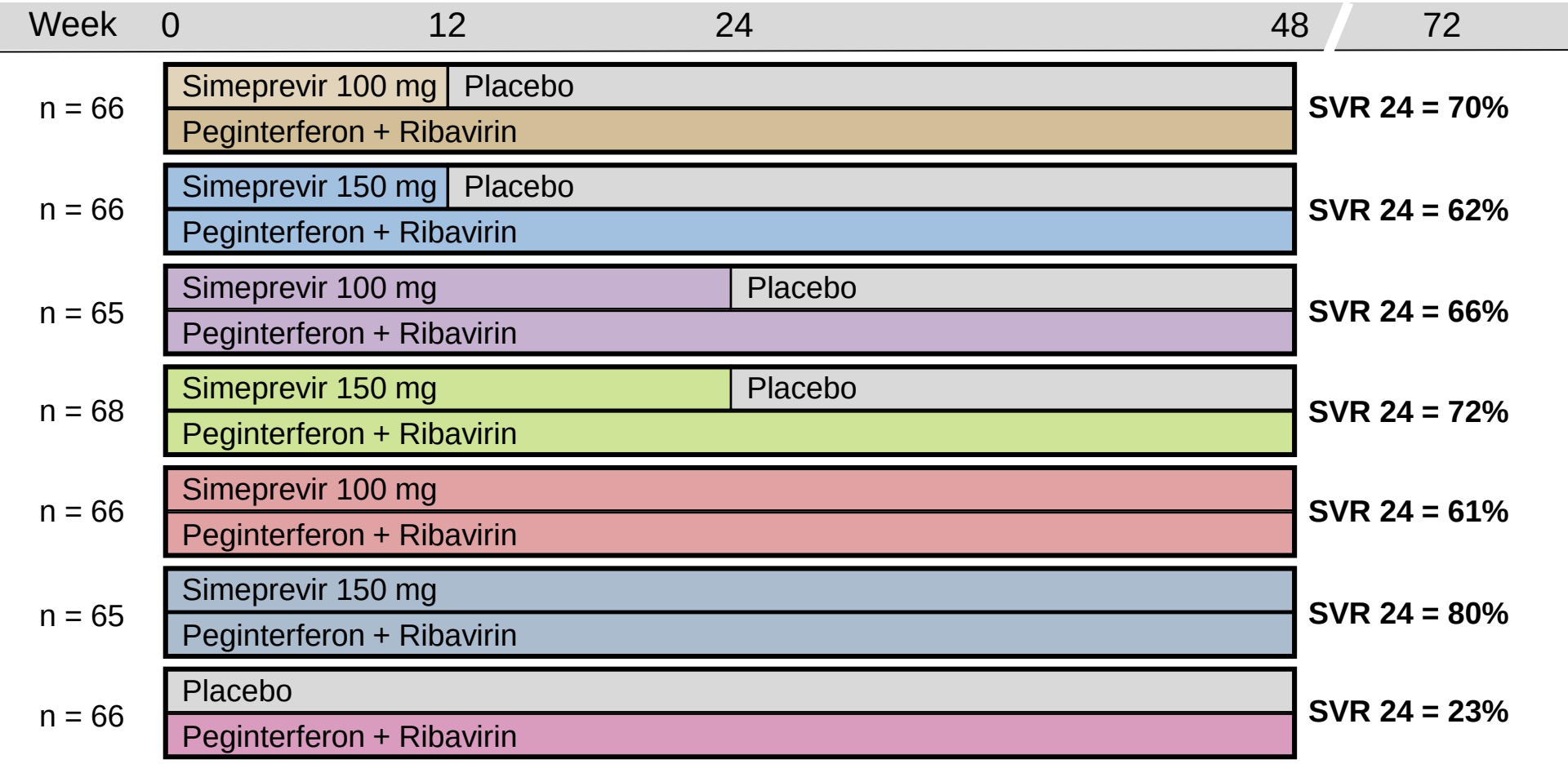
Simeprevir in Treatment Experienced Genotype 1 HCV
ASPIRE Trial: Results



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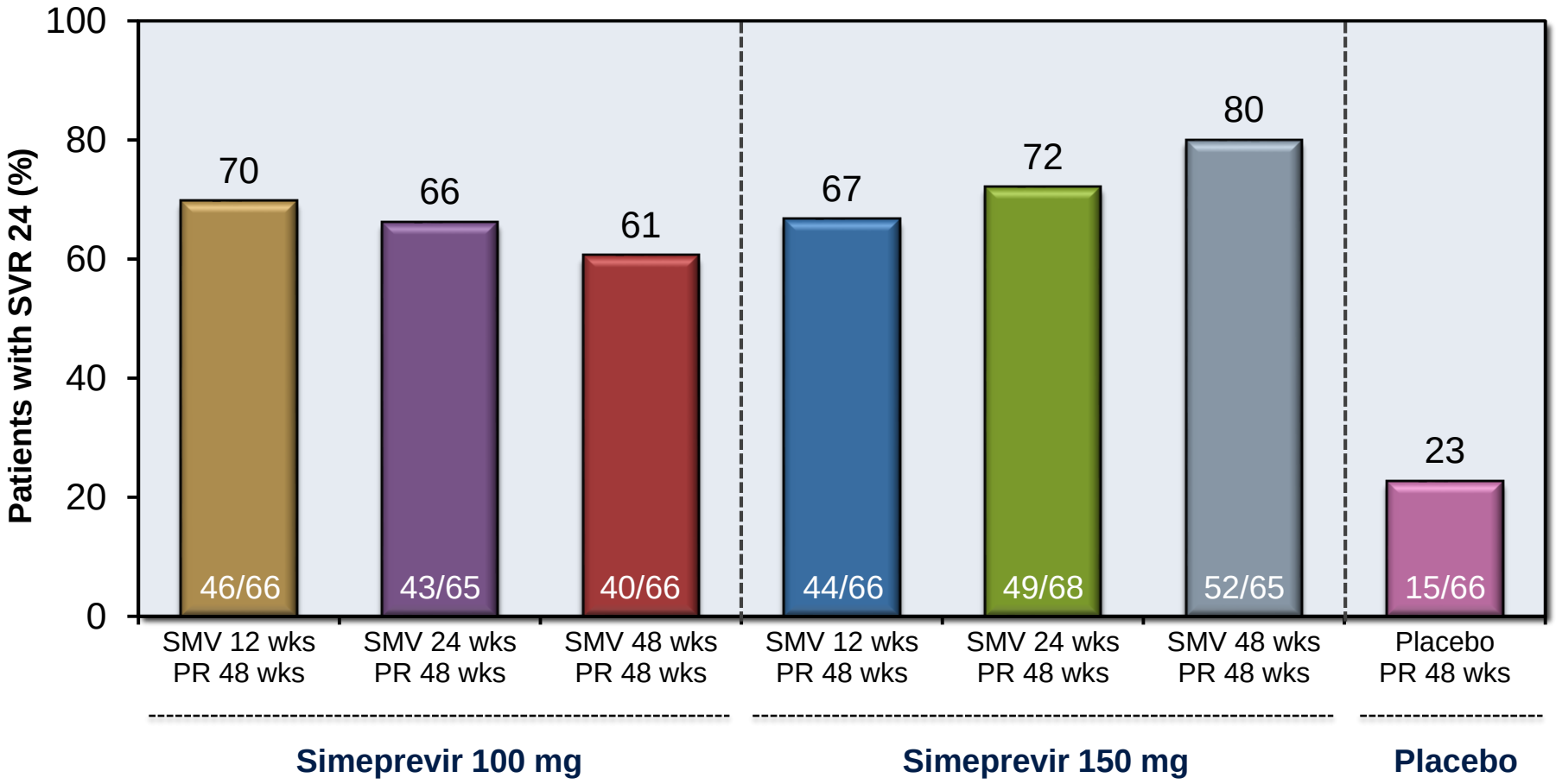
Simeprevir in Treatment Experienced Genotype 1 HCV
ASPIRE Trial: Results

ASPIRE: SVR 24, by Treatment Regimen



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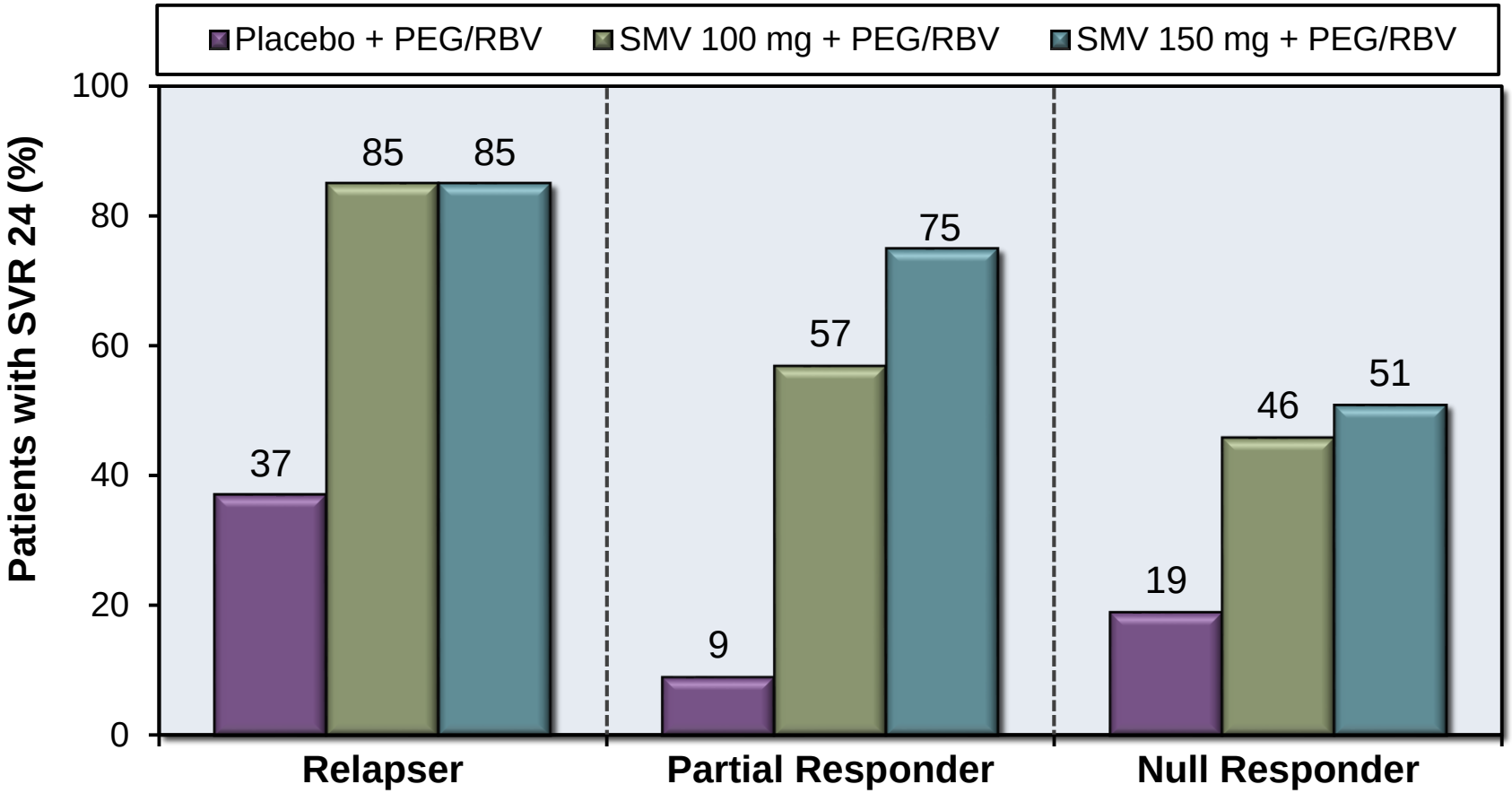
Hepatitis web study

Simeprevir in Treatment Experienced Genotype 1 HCV
ASPIRE Trial: Results

ASPIRE: SVR 24, by Prior Treatment Response



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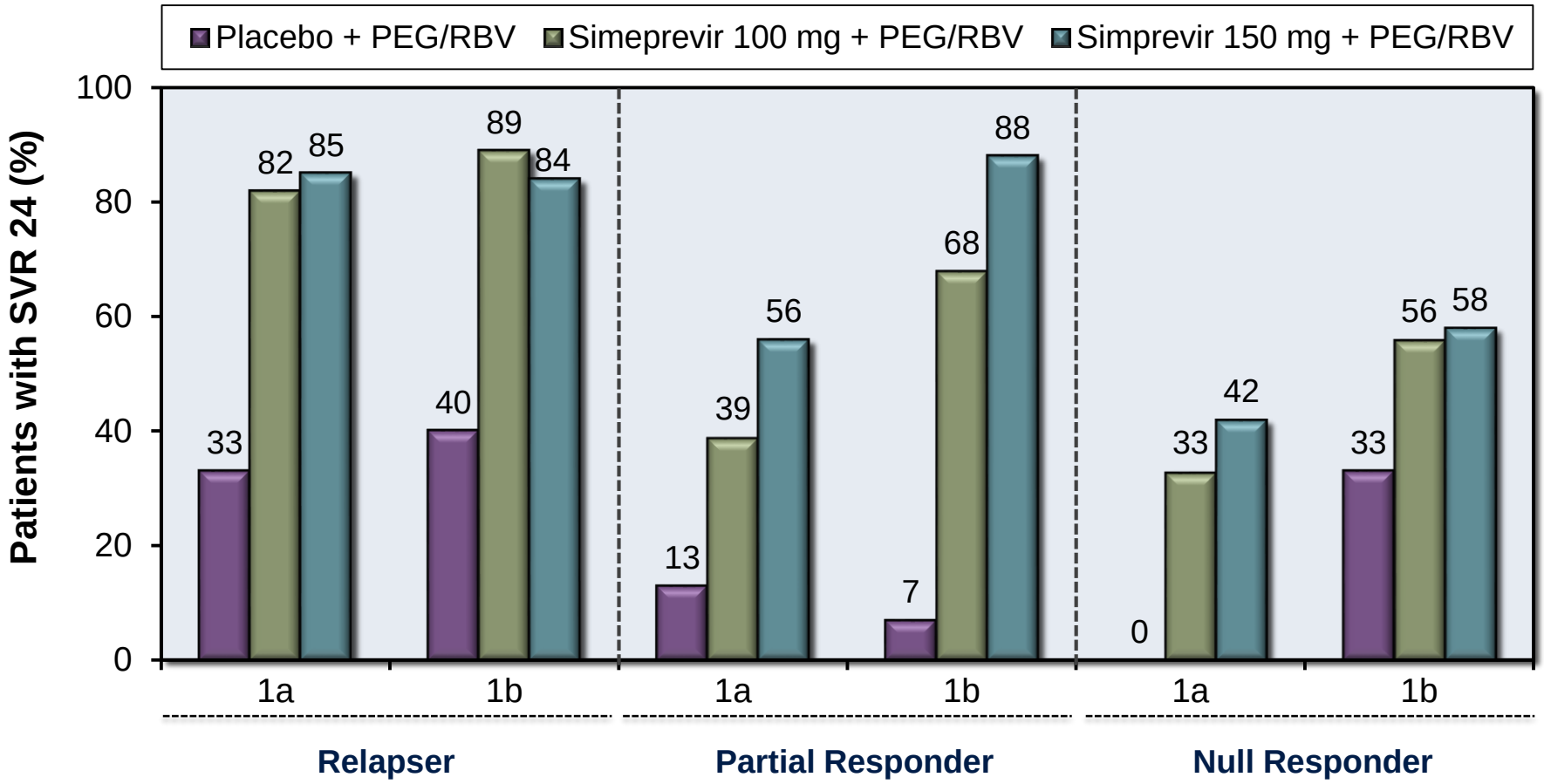
Simeprevir in Treatment Experienced Genotype 1 HCV
ASPIRE Trial: Results

ASPIRE: SVR 24, by Prior Treatment Response and GT 1 Subtype



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Simeprevir in Treatment Experienced Genotype 1 HCV ASPIRE Trial: Conclusions

Conclusion: “In treatment-experienced patients, 12, 24, or 48 weeks simeprevir (100 mg or 150 mg once daily) in combination with 48 weeks peginterferon and ribavirin significantly increased rates of SVR at 24 weeks compared with patients given placebo, peginterferon, and ribavirin, and was generally well tolerated.”

Source: Zeuzem S, et al. Gastroenterol. 2014;146:430-41.

This slide deck is from the University of Washington's *Hepatitis C Online* and *Hepatitis Web Study* projects.

Hepatitis C Online

www.hepatitisc.uw.edu

Hepatitis Web Study

http://depts.washington.edu/hepstudy/

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Hepatitis web study