Treatment Experienced

Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + RBV in GT1

SAPPHIRE-II

Zeuzem S, et al. N Engl J Med. 2014;370:1604-14.

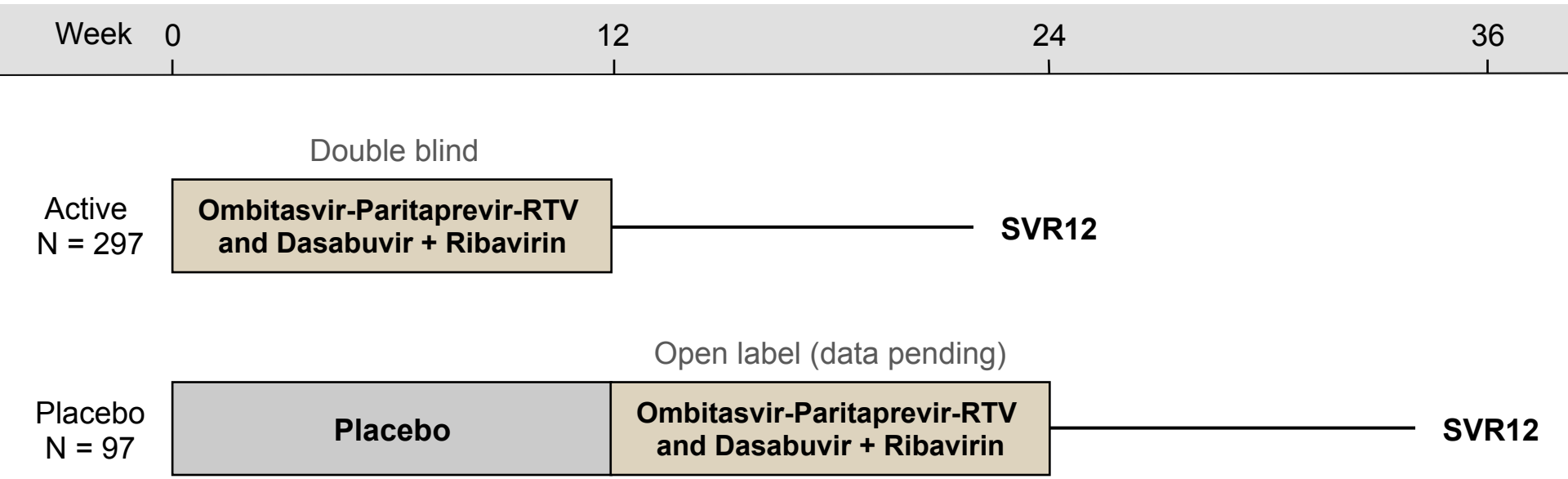
Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + RBV in GT1
SAPPHIRE-II: Study Design

SAPPHIRE-II: Features

- **Design**: Phase 3, randomized, open-label trial evaluating safety and efficacy of ombitasvir-paritaprevir-ritonavir and dasabuvir + ribavirin for 12 weeks in treatment-experienced patients with chronic HCV genotype 1
- **Setting**: 76 sites in Australia, North America, and Europe
- **Entry Criteria**
  - Chronic HCV infection with genotype 1
  - Prior treatment experience with peginterferon plus ribavirin
  - Age 18-70
  - Plasma HCV RNA greater than 10,000 IU/mL
  - Absence of cirrhosis
  - Absence of coinfection with HBV or HIV
- **Primary End-Point**: SVR12

Source: Zeuzem S, et al. N Engl J Med. 2014;370:1604-14.

Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + RBV in GT1
SAPPHIRE-II: Regimens



RTV = Ritonavir

Drug Dosing

Ombitasvir-Paritaprevir-Ritonavir (25/150/100 mg once daily) + Dasabuvir: 250 mg twice daily

Ribavirin (RBV): weight-based and divided bid (1000 mg/day if < 75kg or 1200 mg/day if ≥ 75kg)

Source: Zeuzem S, et al. N Engl J Med. 2014;370:1604-14.

Ombitasvir-Paritaprevir-Ritonavir + Dasabuvir + RBV in GT1 SAPPHIRE-II Study: Baseline Characteristics

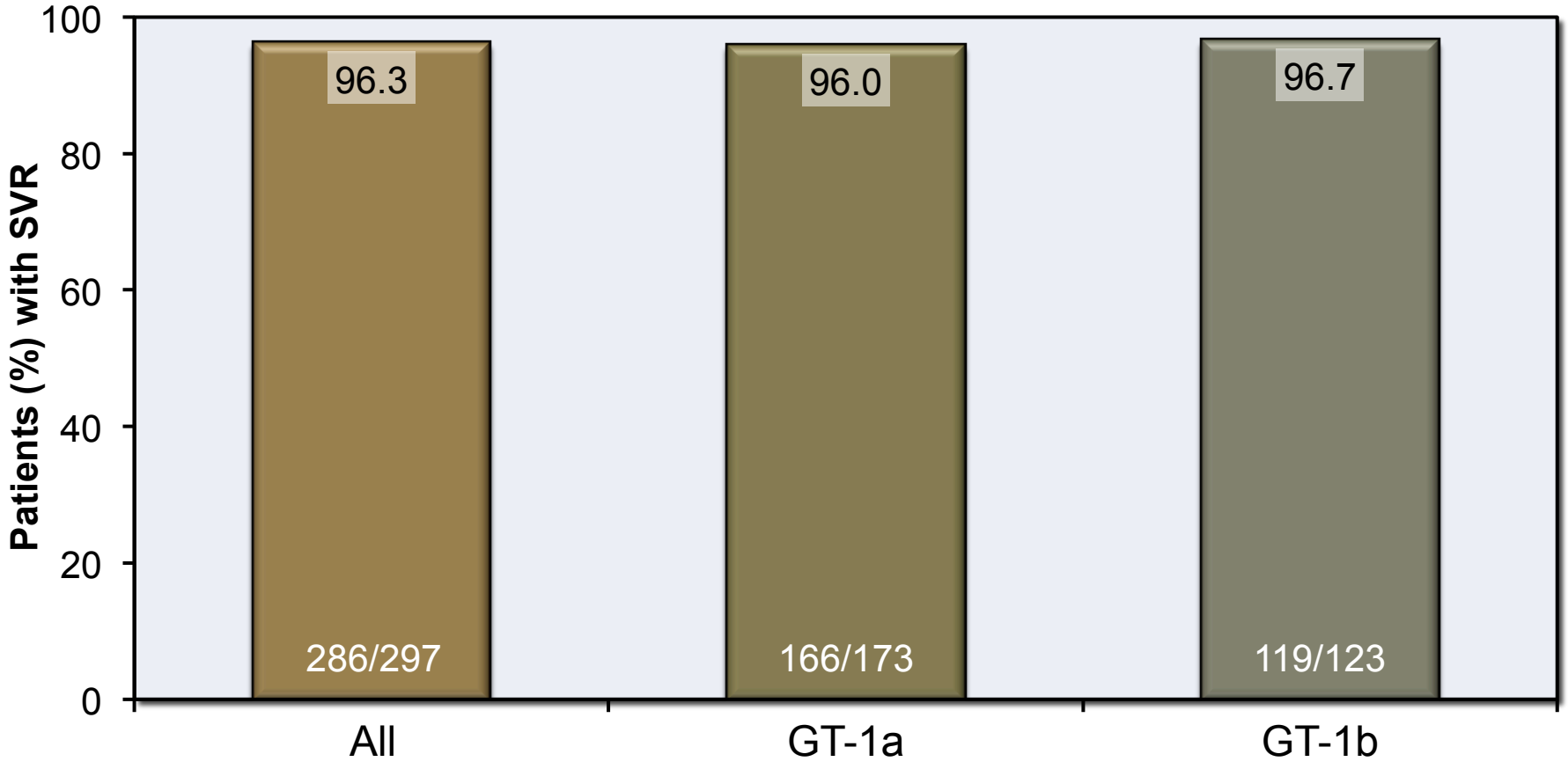
Baseline Characteristic	3D + RBV (n=297)	Placebo Arm (n=97)
Age (years), Mean	51.7	54.9
Male sex %	56.2	61.9
Race (%) White Black Asian	 90.6 7.4 2.0	 88.7 10.3 0
Body Mass Index (Mean)	26.3	26.4
HCV genotype (%) 1a 1b	 58.2 41.4	 58.8 41.2
IL28B CC genotype, (%)	11.4	7.2
Type of Prior Response Relapse Partial Response Null Response	 29.0 21.9 49.2	 29.9 21.6 48.5
HCV RNA, $\log_{10}$ IU/ml (mean)	6.55	6.52
Fibrosis score F2 or F3 (%)	32.0	33.0

3D = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir; **RBV** = Ribavirin

Source: Zeuzem S, et al. N Engl J Med. 2014;370:1604-14.

Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + RBV in GT1
SAPPHIRE-II: Results

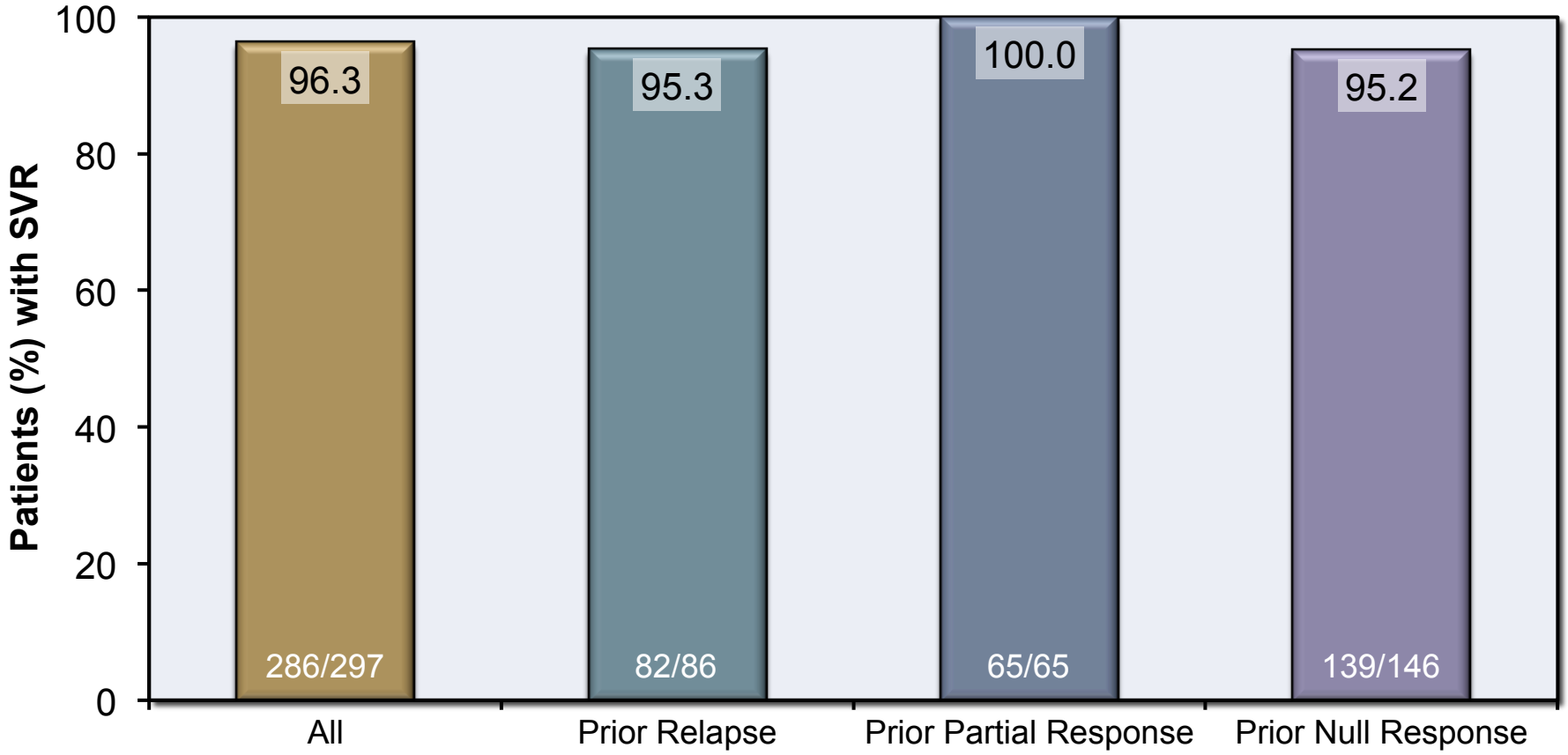
SAPPHIRE-II: Results by Genotype 1 Subtype



Source: Zeuzem S, et al. N Engl J Med. 2014;370:1604-14.

Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + RBV in GT1
SAPPHIRE-II: Results

SAPPHIRE-II: Results by Prior Treatment Response



Source: Zeuzem S, et al. N Engl J Med. 2014;370:1604-14.

Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + RBV in GT1 SAPPHIRE-II Study: Key Adverse Events

Event	3D + RBV (n=297)	Placebo (n=97)
Any adverse events %	91.2	82.5
Any serious adverse event %	2.0	1.0
Common adverse events:		
Headache %	36.4	35.1
Fatigue %	33.3	22.7
Nausea %	20.2	17.5
Asthenia %	15.8	11.3
Insomnia %	14.1	7.2
Pruritus %	13.8	5.2
Diarrhea %	13.1	12.4
Dyspnea %	12.5	10.3
Cough %	10.8	5.2
Myalgia %	7.7	10.3
Abnormalities in laboratory values of grade 3 or 4 %		
Alanine aminotransferase	1.7	3.1
Total bilirubin	2.4	0

3D = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir; **RBV** = Ribavirin

Source: Zeuzem S, et al. N Engl J Med. 2014;370:1604-14.

Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + RBV in GT1
SAPPHIRE-II: Conclusions

Conclusions: “Rates of response to a 12-week interferon-free combination regimen were more than 95% among previously treated patients with HCV genotype 1 infection, including patients with a prior null response.”

Source: Zeuzem S, et al. N Engl J Med. 2014;370:1604-14.

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