Treatment Naïve

Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + RBV in GT1

SAPPHIRE-I

Feld JJ, et al. N Engl J Med. 2014;370:1594-1603.

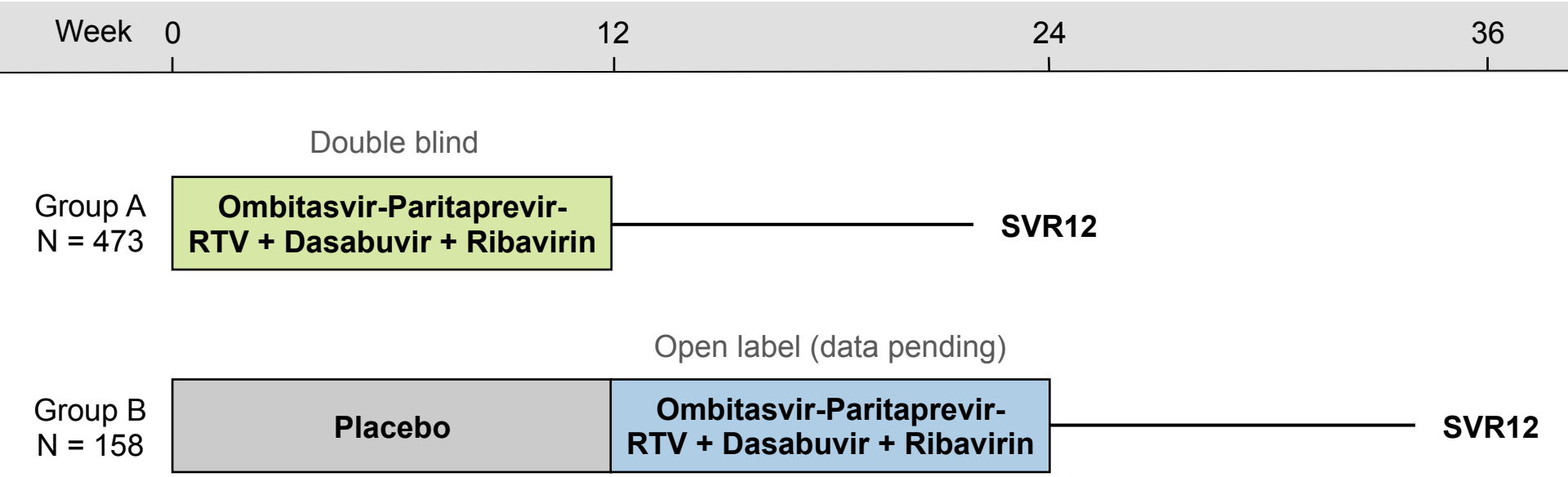
Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + Ribavirin in GT1
SAPPHIRE-I Study: Design

SAPPHIRE-I: Features

- **Design**: Phase 3, randomized, double-blind, placebo-controlled trial evaluating safety and efficacy of ombitasvir-paritaprevir-ritonavir and dasabuvir + ribavirin for 12 weeks in treatment-naïve patients with chronic hepatitis C virus genotype 1
- **Setting**: International at 79 sites in North America, Europe, and Australia
- **Entry Criteria**
  - Chronic HCV infection with genotype 1a or 1b
  - Treatment-naïve
  - 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: Feld JJ, et al. N Engl J Med. 2014;370:1594-1603.

Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + Ribavirin in GT1
SAPPHIRE-I Study: Study 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 < 75 kg or 1200 mg/day if ≥ 75 kg)

Source: Feld JJ, et al. N Engl J Med. 2014;370:1594-1603.

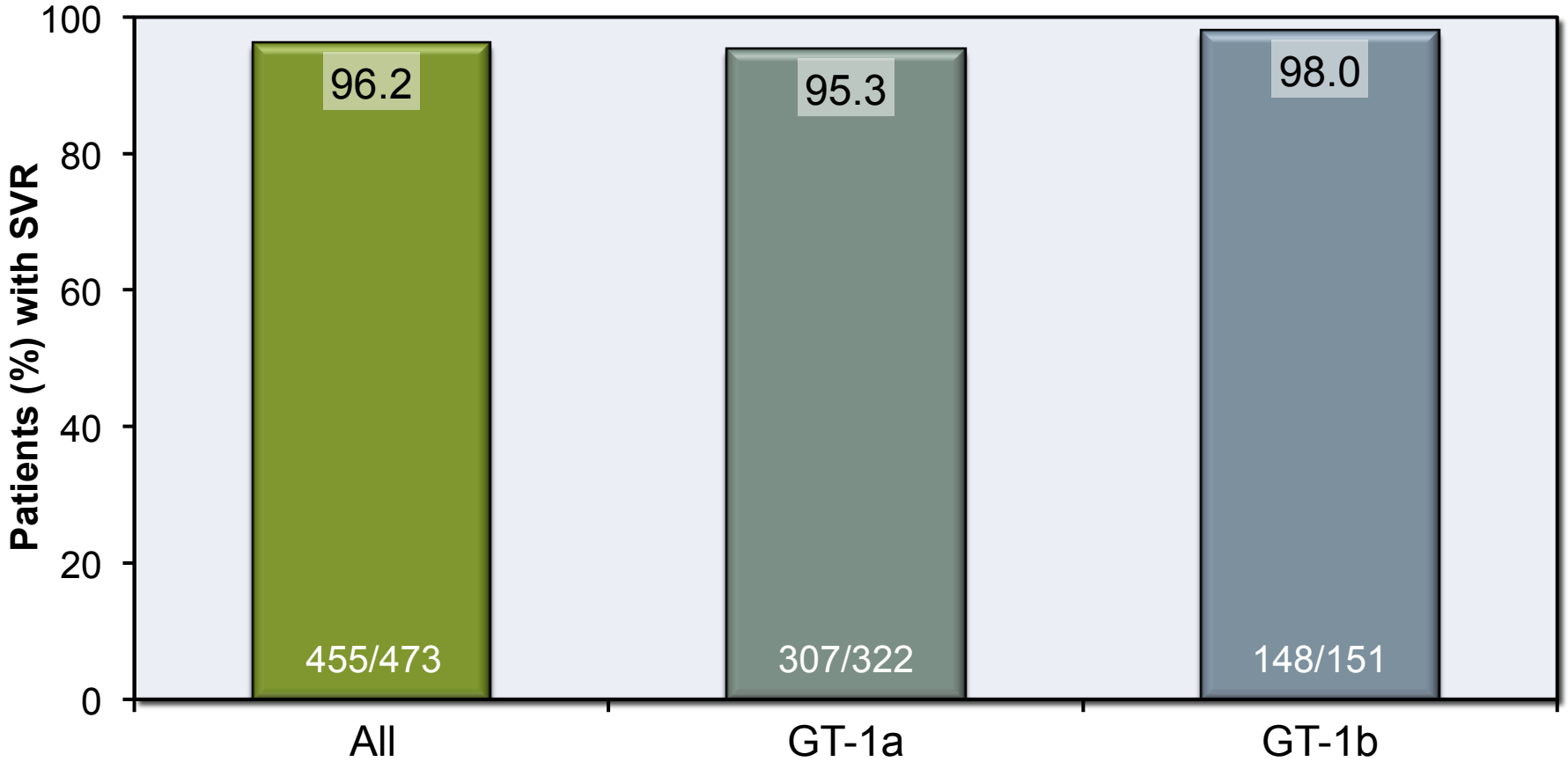
Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + Ribavirin in GT1
SAPPHIRE-I Study: Baseline Characteristics

Baseline Characteristic	Group A (N=473)	Group B (N=158)
Age (years), Mean	49.4	51.2
Male sex %	57.3	46.2
Race (%)		
White	90.5	91.1
Black	5.5	5.1
Other	4.0	3.8
Body Mass Index (Mean)	25.7	26.2
HCV genotype (%)		
1a	68.1	66.5
1b	31.9	33.5
IL28B CC genotype, (%)	30.4	31.6
HCV RNA, $\log_{10}$ IU/ml	6.40	6.47
Fibrosis score ≥ F2	23.3	26.6

Source: Feld JJ, et al. N Engl J Med. 2014;370:1594-1603.

Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + Ribavirin in GT1
SAPPHIRE-I Study: Results

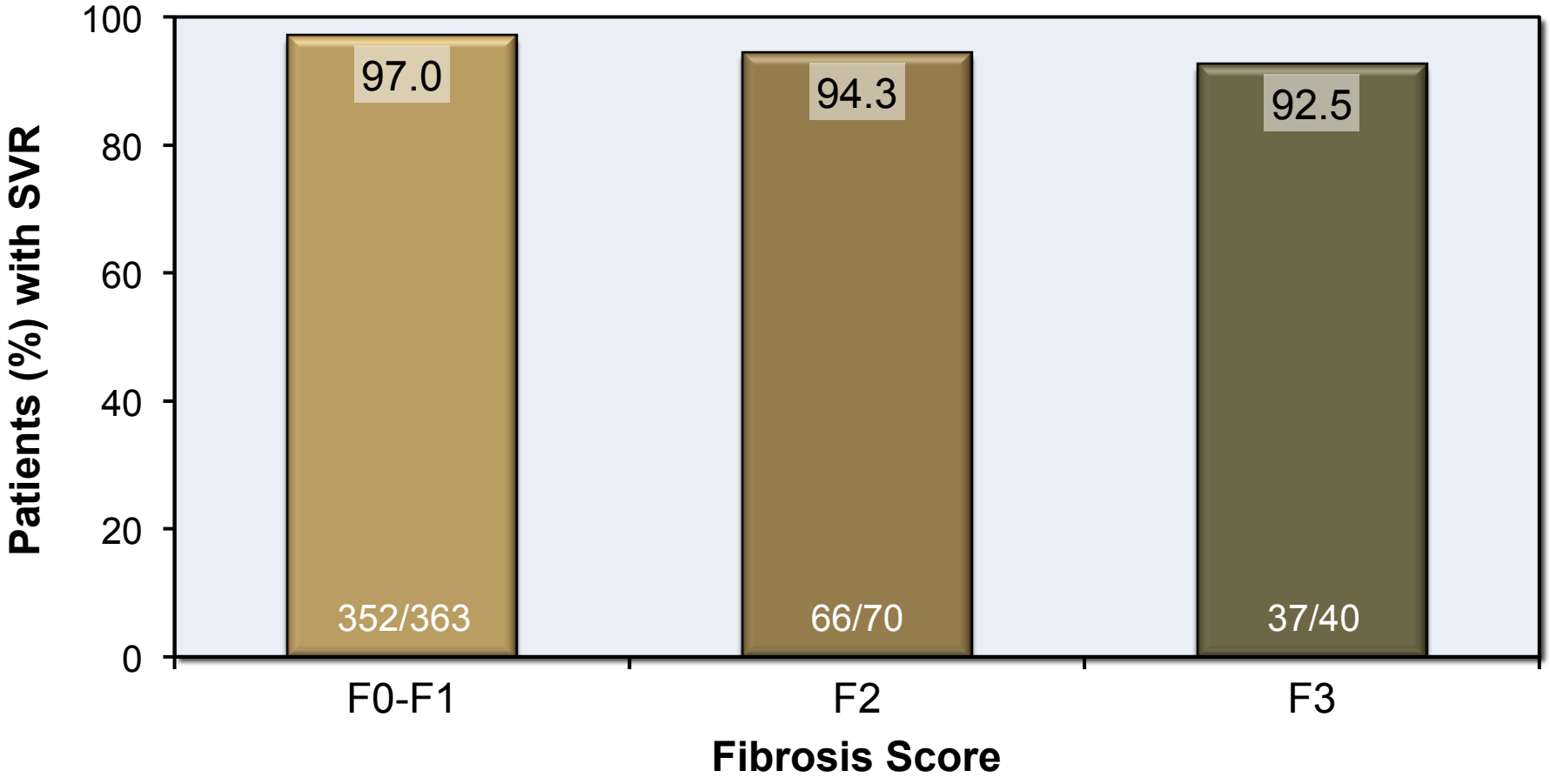
SAPPHIRE-I: SVR12 in Group A, by Genotype 1 Subtype



Source: Feld JJ, et al. N Engl J Med. 2014;370:1594-1603.

Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + Ribavirin in GT1
SAPPHIRE-I Study: Results

SAPPHIRE-I: SVR12 in Group A, Fibrosis Score



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Hepatitis web study

Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + Ribavirin in GT1
SAPPHIRE-I Study: Adverse Events During Double-Blind Phase

Event	Group A = 3D + RBV (N=473)	Group B = Placebo (N=158)
Any adverse event (%)	87.5	73.4
Any adverse event leading to discontinuation of study drug (%)	0.6	0.6
Any serious adverse event (%)	2.1	0
Grade 3 or 4 lab abnormality (%)		
Alanine aminotransferase	0.9	4.4
Aspartate aminotransferase	0.6	1.9
Alkaline phosphatase	0	0
Total bilirubin	2.8	0
Hemoglobin	0	0

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

Source: Feld JJ, et al. N Engl J Med. 2014;370:1594-1603.

Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir + Ribavirin in GT1 SAPPHIRE-I Study: Conclusions

Conclusions: “In previously untreated patients with HCV genotype 1 infection and no cirrhosis, a 12-week multitargeted regimen of ABT-450/r–ombitasvir and dasabuvir with ribavirin was highly effective and was associated with a low rate of treatment discontinuation.”

Note: ABT-450/r = Paritaprevir-Ritonavir

Source: Feld JJ, et al. N Engl J Med. 2014;370:1594-1603.

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