

Treatment Naïve and Treatment Experienced

Sofosbuvir in Genotypes 2 or 3 VALENCE Trial

Zeuzem S, et al. N Engl J Med. 2014;370:1993-2001

Sofosbuvir and Ribavirin for HCV GT 2 or 3

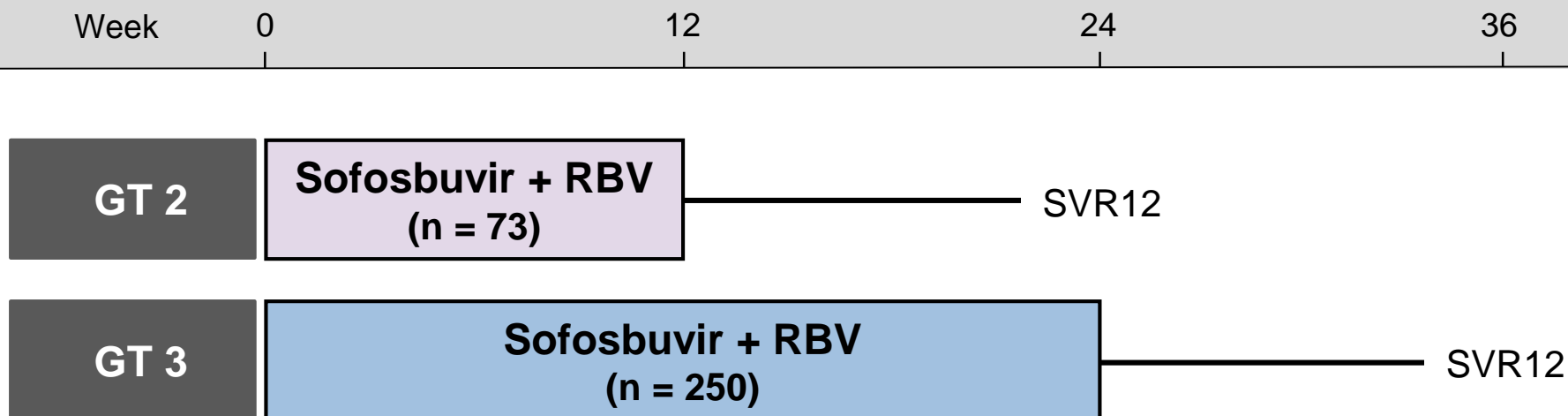
VALENCE Trial: Study Features

VALENCE Trial: Features

- **Design:** Randomized, phase 3, using sofosbuvir + ribavirin in treatment naïve or experienced, chronic HCV GT 2 or 3
- **Setting:** Europe
- **Entry Criteria**
 - Chronic HCV Genotype 2 or 3
 - Treatment naïve or treatment experienced
 - Platelet \geq 50,000
- **Patient Characteristics (range in different treatment arms)**
 - N = 419
 - Sex: male (55-62%)
 - Race: white (89-100%)
 - Cirrhosis: (14-23%)
 - IL28B Genotype: non-CC (64-74%)
- **End-Points:** Primary = SVR12; Secondary = safety

Sofosbuvir and Ribavirin for HCV GT 2 or 3

VALENCE: Treatment Arms



Note: 85 patients enrolled in placebo arm

Original Study Protocol: Placebo versus 12 weeks treatment for GT 2 and 3.

Amended Protocol: GT3 treatment extended from 12 to 24 weeks; Placebo arm offered alternative treatment

Drug Dosing

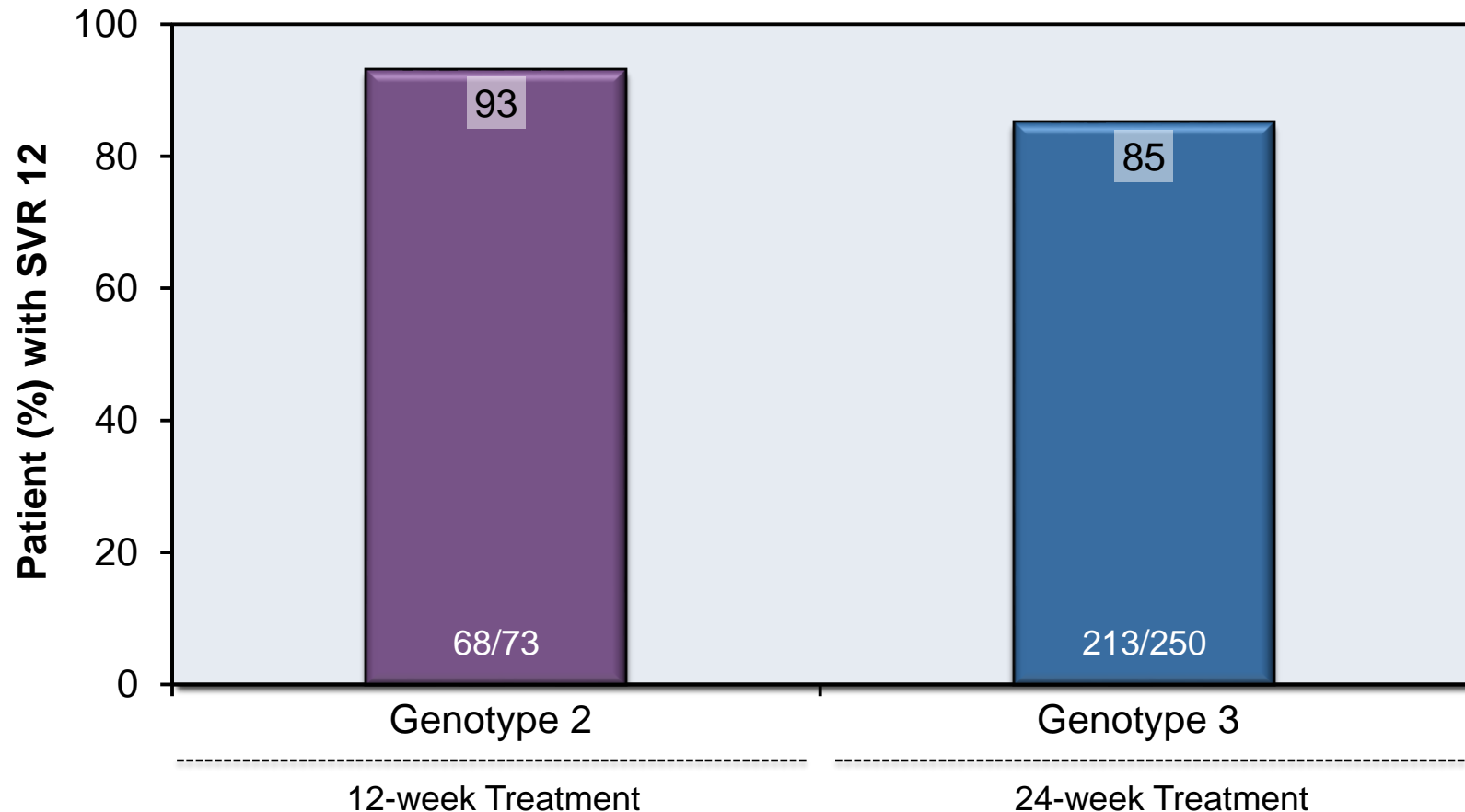
Sofosbuvir 400 mg once daily

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

Sofosbuvir and Ribavirin for HCV GT 2 or 3

VALENCE: Results for Treatment Naïve and Experienced

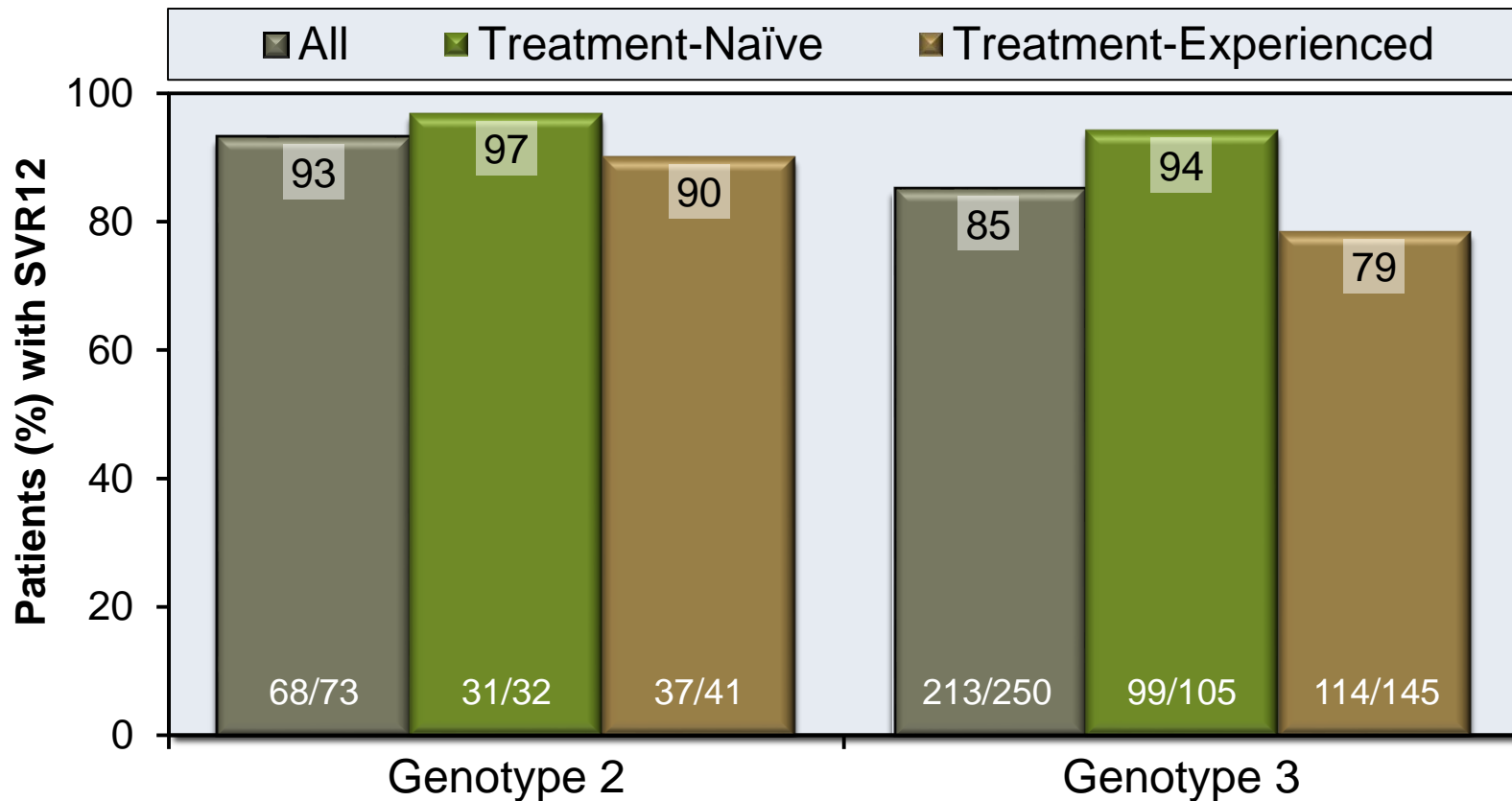
VALENCE: SVR12 by Genotype



Sofosbuvir and Ribavirin for HCV GT 2 or 3

VALENCE: Results

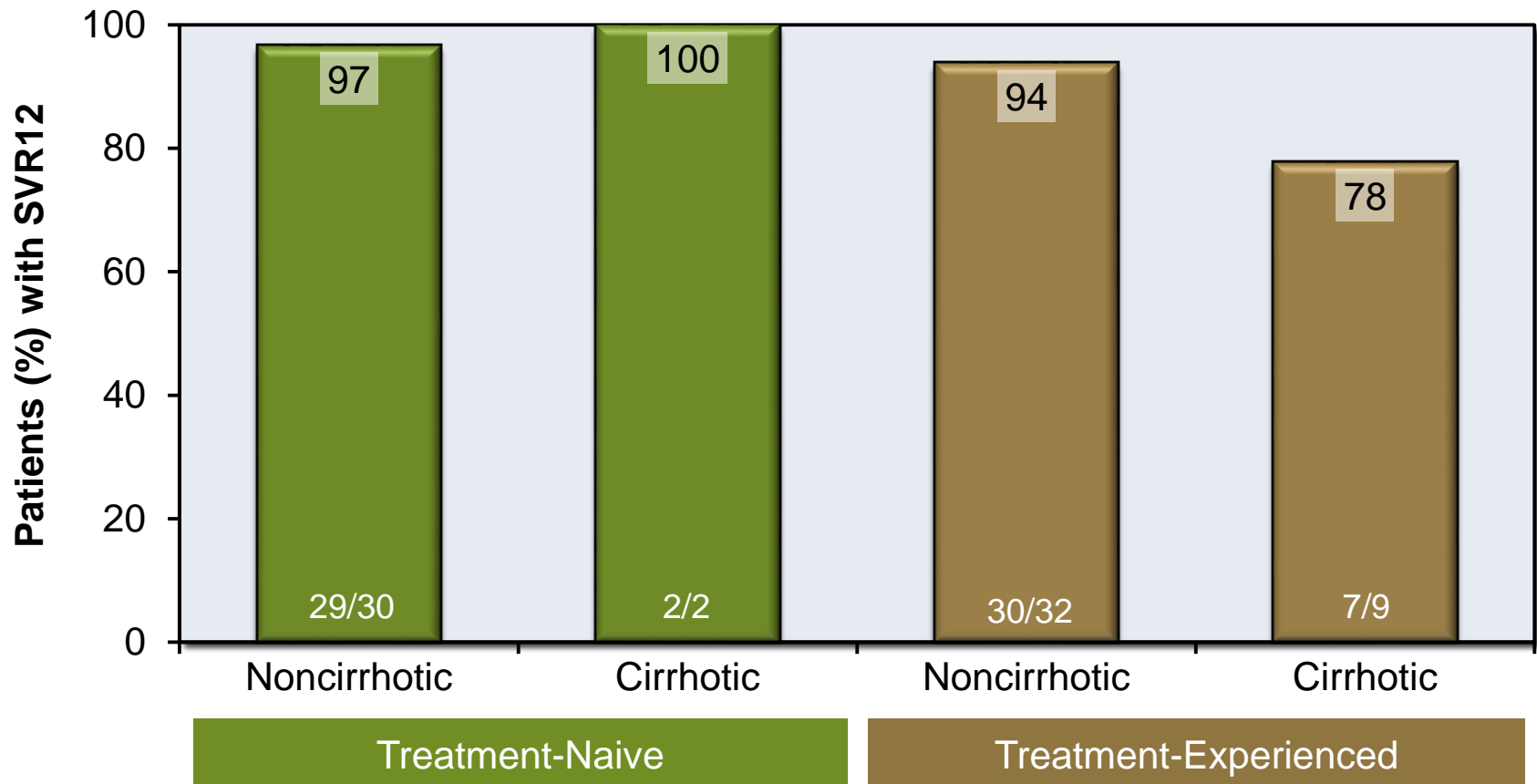
VALENCE: SVR12 by Genotype and Prior Treatment Experience



Sofosbuvir and Ribavirin for HCV GT 2 or 3

VALENCE: Results for GT 2

VALENCE: GT 2 SVR12, by Treatment Experience & Liver Disease

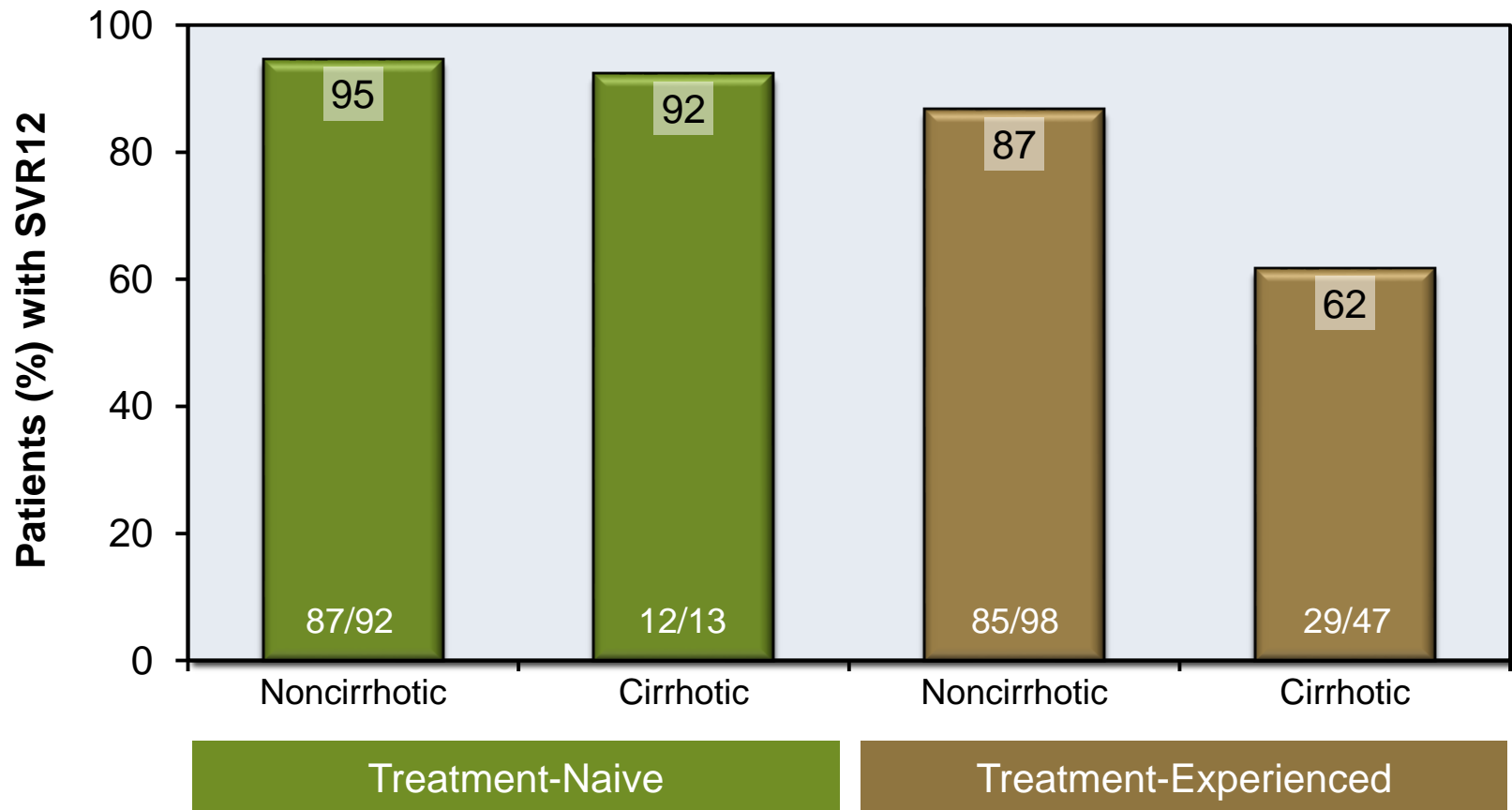


Source: Zeuzem S, et al. N Engl J Med. 2014;370:1993-2001.

Sofosbuvir and Ribavirin for HCV GT 2 or 3

VALENCE: Results for GT 3

VALENCE: GT 3 SVR12, by Treatment Experience & Liver Disease



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Sofosbuvir and Ribavirin for HCV GT 2 or 3 VALENCE: Conclusions

Conclusions: “Therapy with sofosbuvir–ribavirin for 12 weeks in patients with HCV genotype 2 infection and for 24 weeks in patients with HCV genotype 3 infection resulted in high rates of sustained virologic response.”

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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