

Treatment Naïve and Treatment Experienced

# Sofosbuvir in Genotypes 2 or 3 VALENCE Trial

Zeuzem S, et al. N Engl J Med. 2014 May 4. [Epub ahead of print]

# Sofosbuvir and Ribavirin for HCV GT 2 or 3

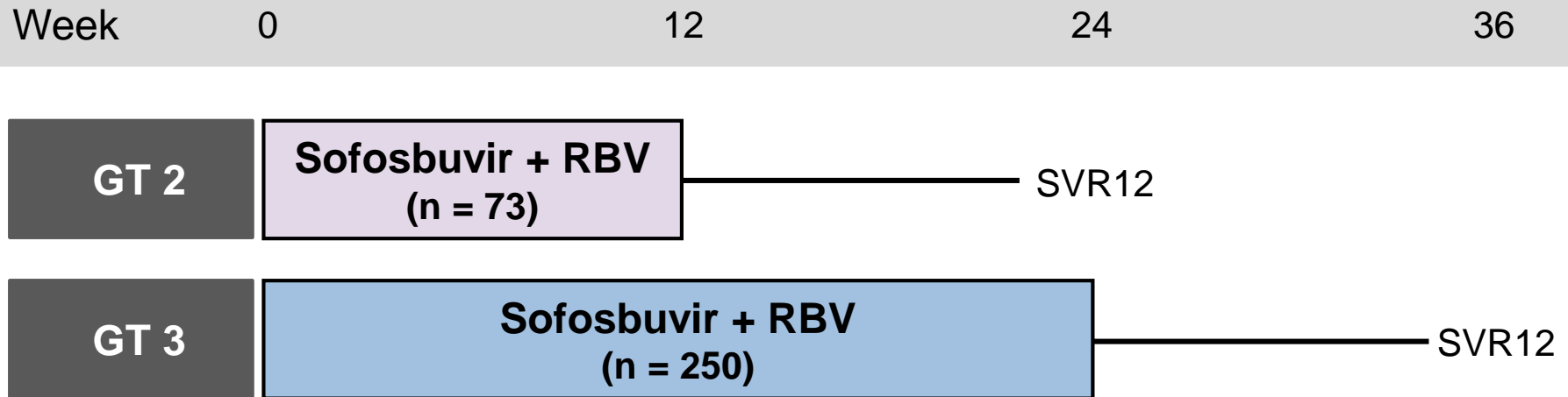
## VALENCE Trial: Study Features

### 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

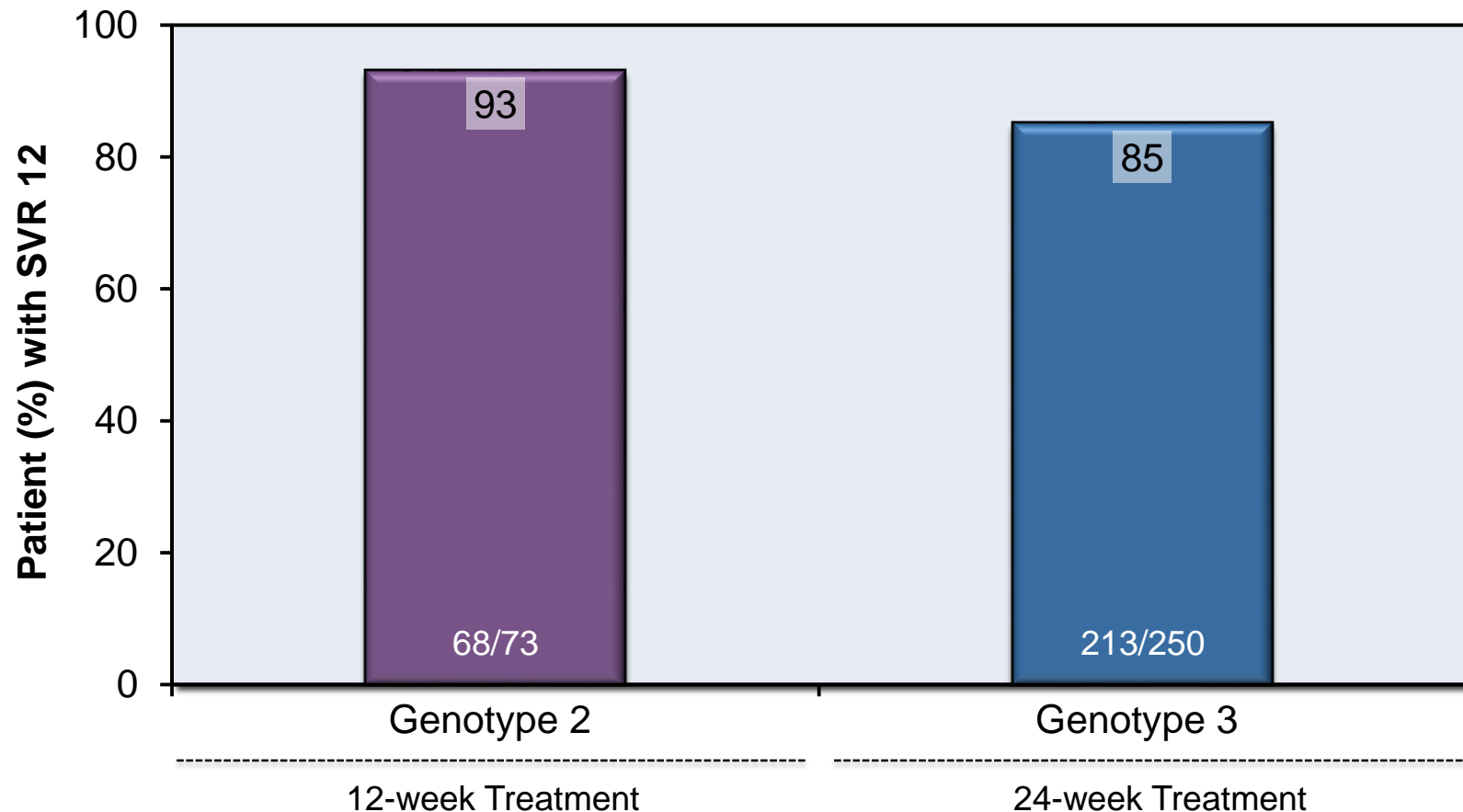
Sofosbuvir 400 mg once daily

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

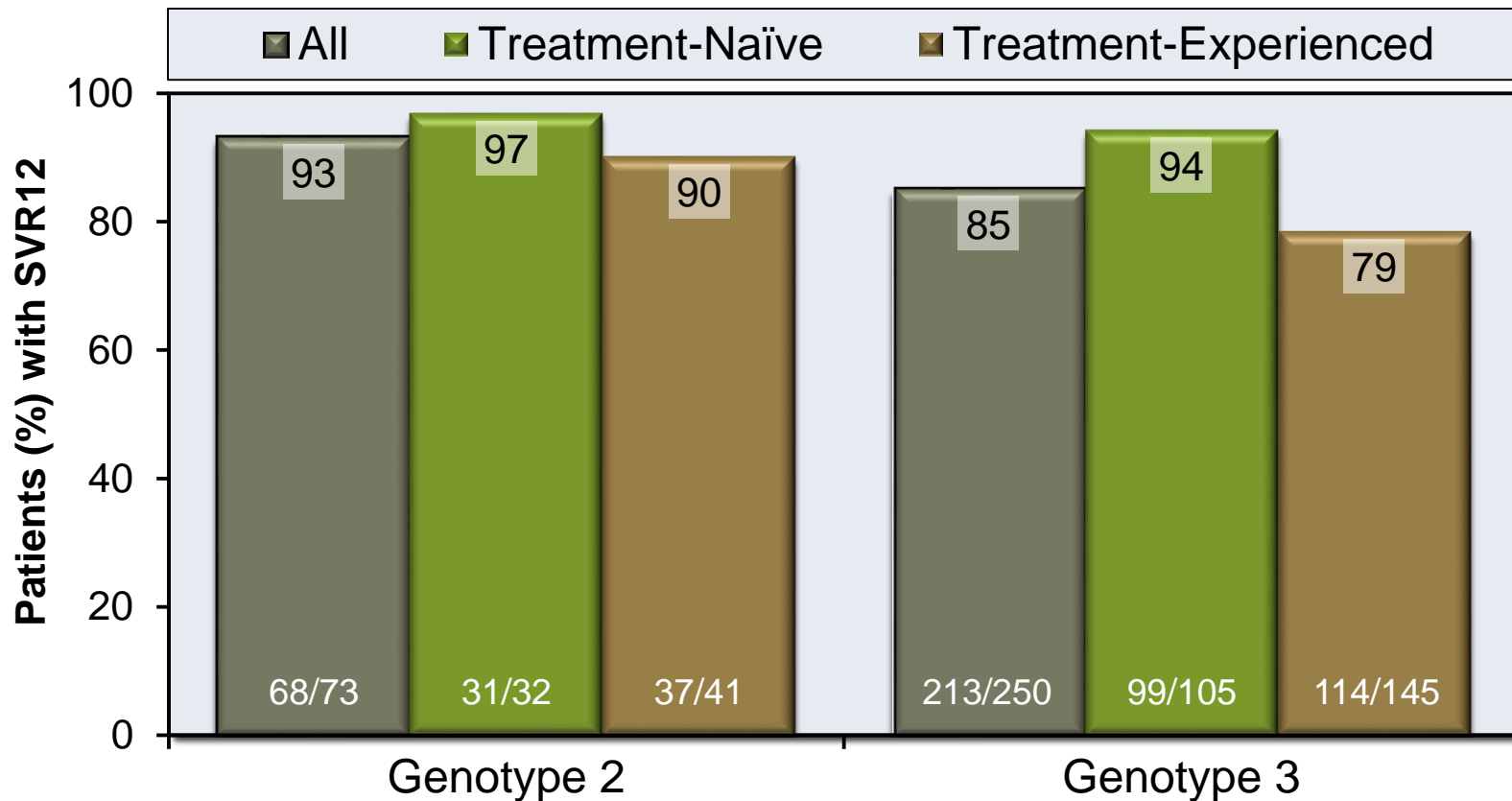
VALENCE: SVR12 by Genotype



# Sofosbuvir and Ribavirin for HCV GT 2 or 3

## VALENCE: Results

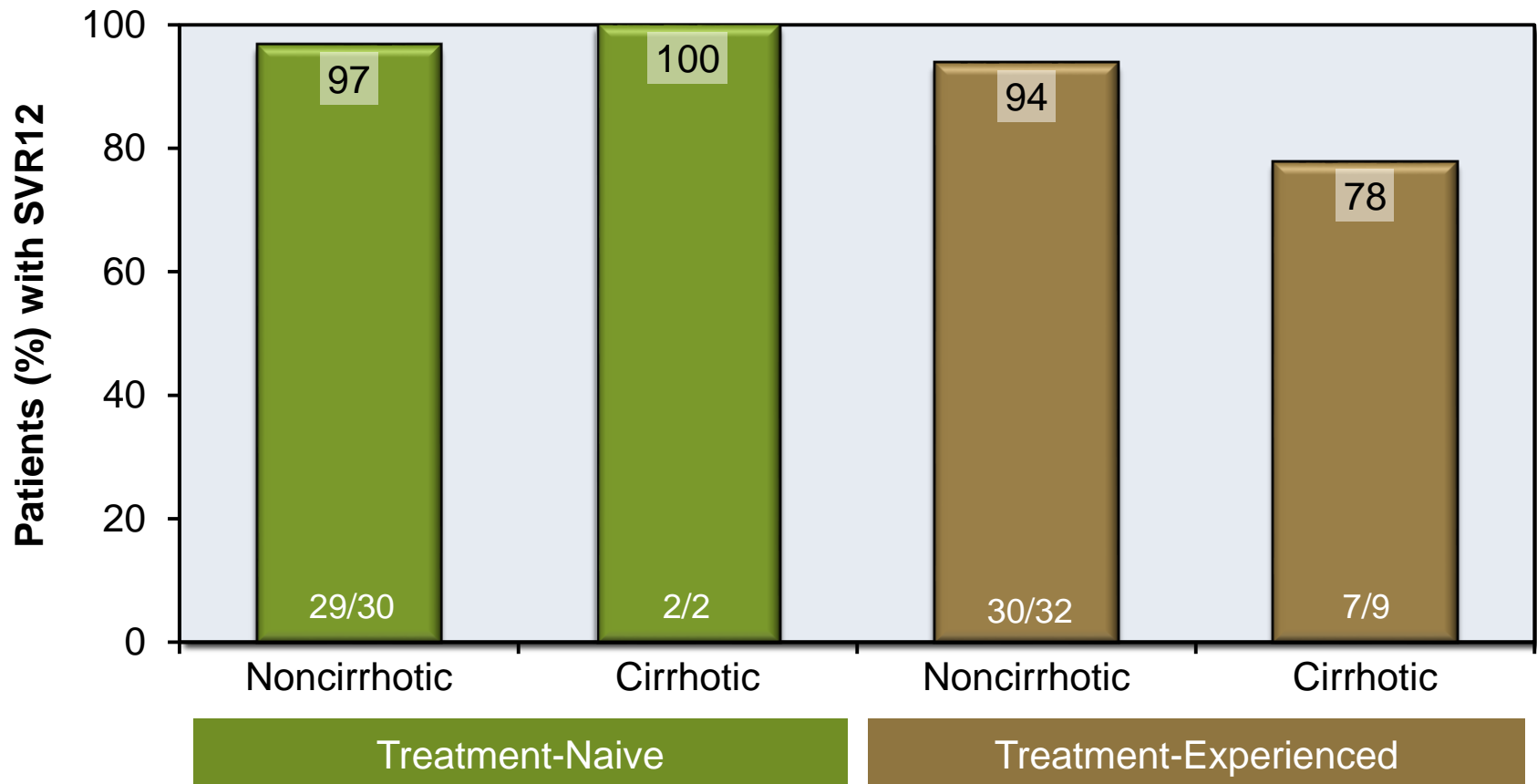
### VALENCE: SVR12 by Genotype and Prior Treatment Experience



# Sofosbuvir and Ribavirin for HCV GT 2 or 3

## VALENCE: Results for GT 2

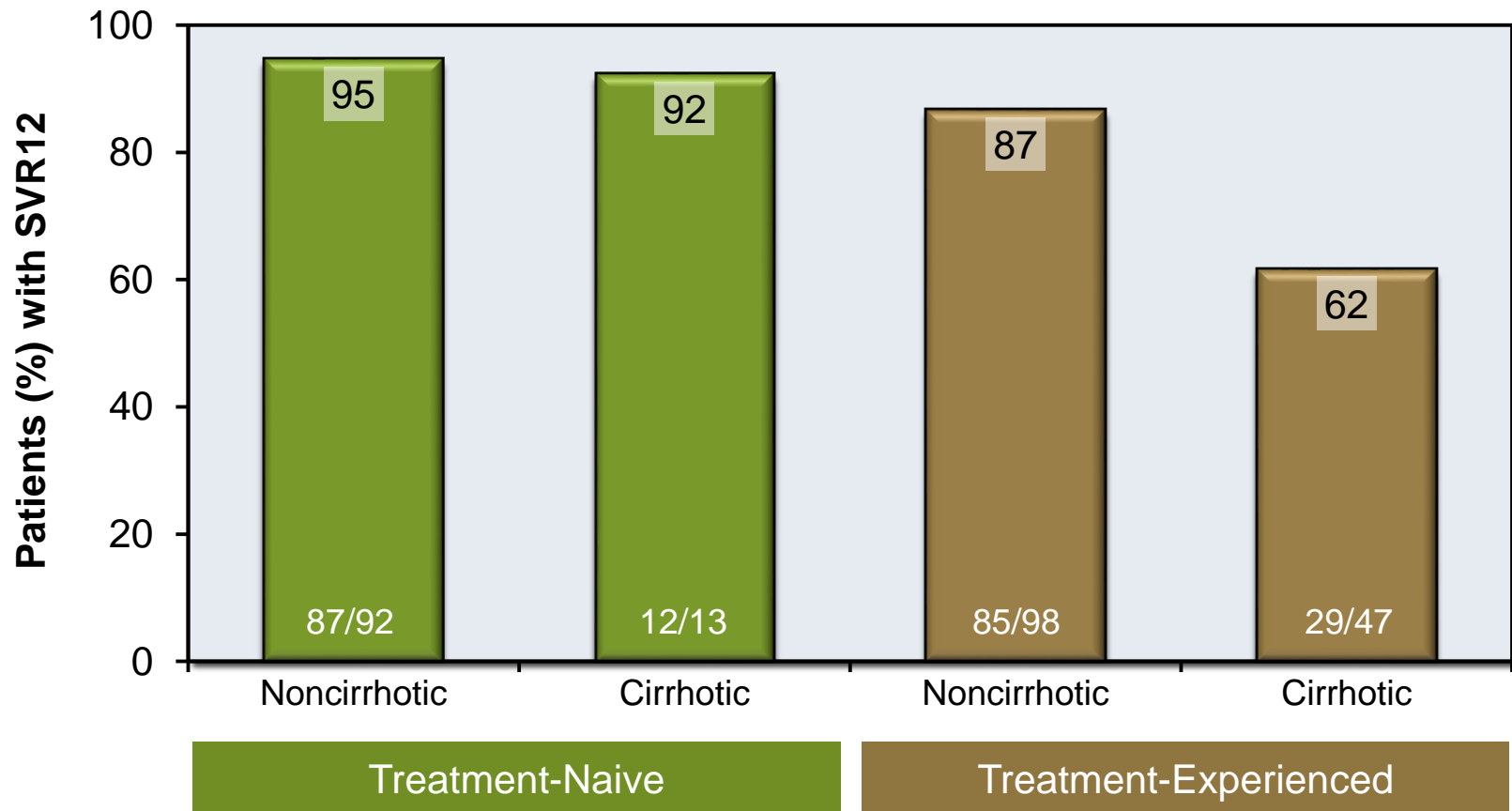
VALENCE: GT 2 SVR12, by Treatment Experience & Liver Disease



# Sofosbuvir and Ribavirin for HCV GT 2 or 3

## VALENCE: Results for GT 3

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



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](http://www.hepatitisc.uw.edu)

Hepatitis Web Study

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

Funded by a grant from the Centers for Disease Control and Prevention.