

Treatment Naïve

Sofosbuvir, Ribavirin, GS-0938 in GT 1-4 QUANTUM

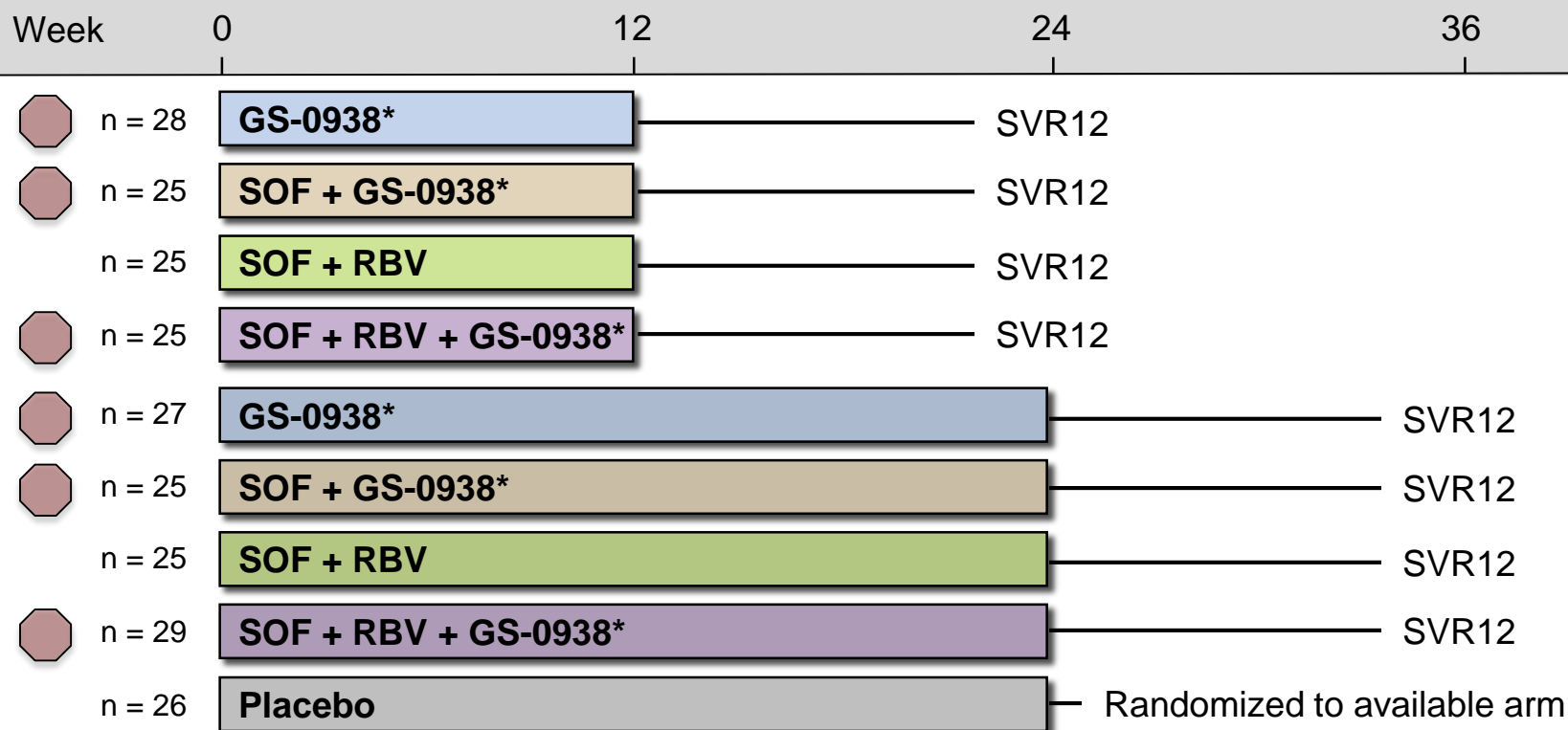
Lalezari JP, et al. EASL. 2013; Abstract 845.

Sofosbuvir, Ribavirin, & GS-0938 in Treatment Naïve QUANTUM Trial: Features

FUSION Trial: Features

- **Design:** Randomized, double-blind, phase 2b trial comparing combinations of sofosbuvir, ribavirin, and GS-0938 in treatment-naïve GT 1-4
- **Setting:** 44 hepatitis C treatment centers in the United States
- **Entry Criteria**
 - Treatment-naïve
 - HCV RNA RNA \geq 50,000 IU/mL
- **Patient Characteristics**
 - N = 235 HCV-monoinfected patients
 - GT-1 = 73-79%; GT-2 = 8-13%; GT-3 = 11-16%; GT-4 = 0-6%
- **Study Modification**
 - All arms with GS-0938 halted due increases in ALT/AST > 5x baseline
 - Patients (n = 132) on GS-0938 regimen who did not achieve SRV retreated with 24 week course of SOF + RBV
- **Primary End-Point:** SVR12

Sofosbuvir, Ribavirin, & GS-0938 in Treatment Naïve QUANTUM Trial: Design



Study Modification: all GS-0938 arms stopped; patients without SVR12 retreated with SOF + RBV x 24 weeks

Drug Dosing

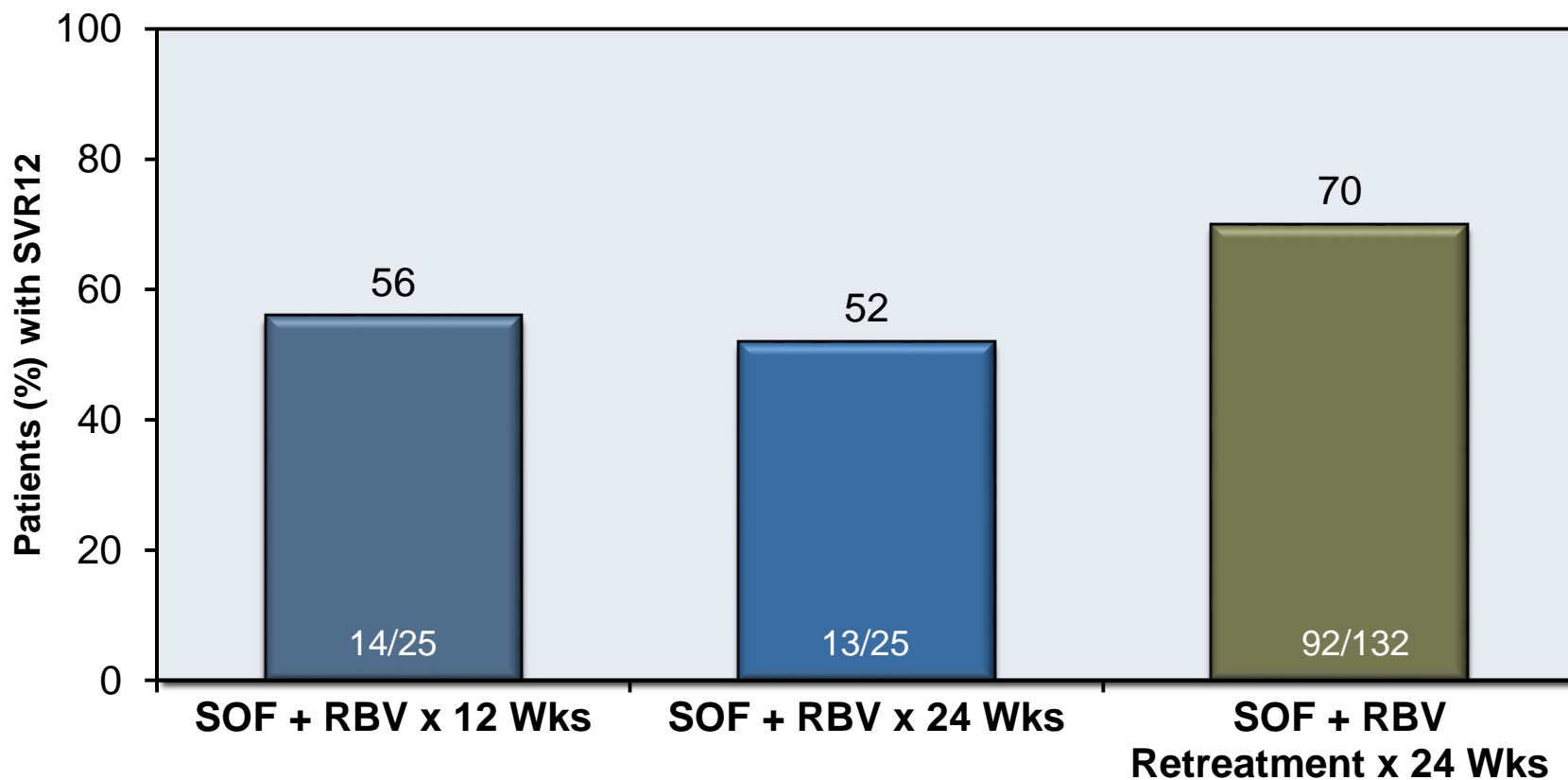
Sofosbuvir (SOF): 400 mg once daily

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

GS-0938: 300 mg once daily

Sofosbuvir, Ribavirin, & GS-0938 in Treatment Naïve QUANTUM Trial: Results

QUANTUM: SVR12 Results for Completed Arms (all genotypes)

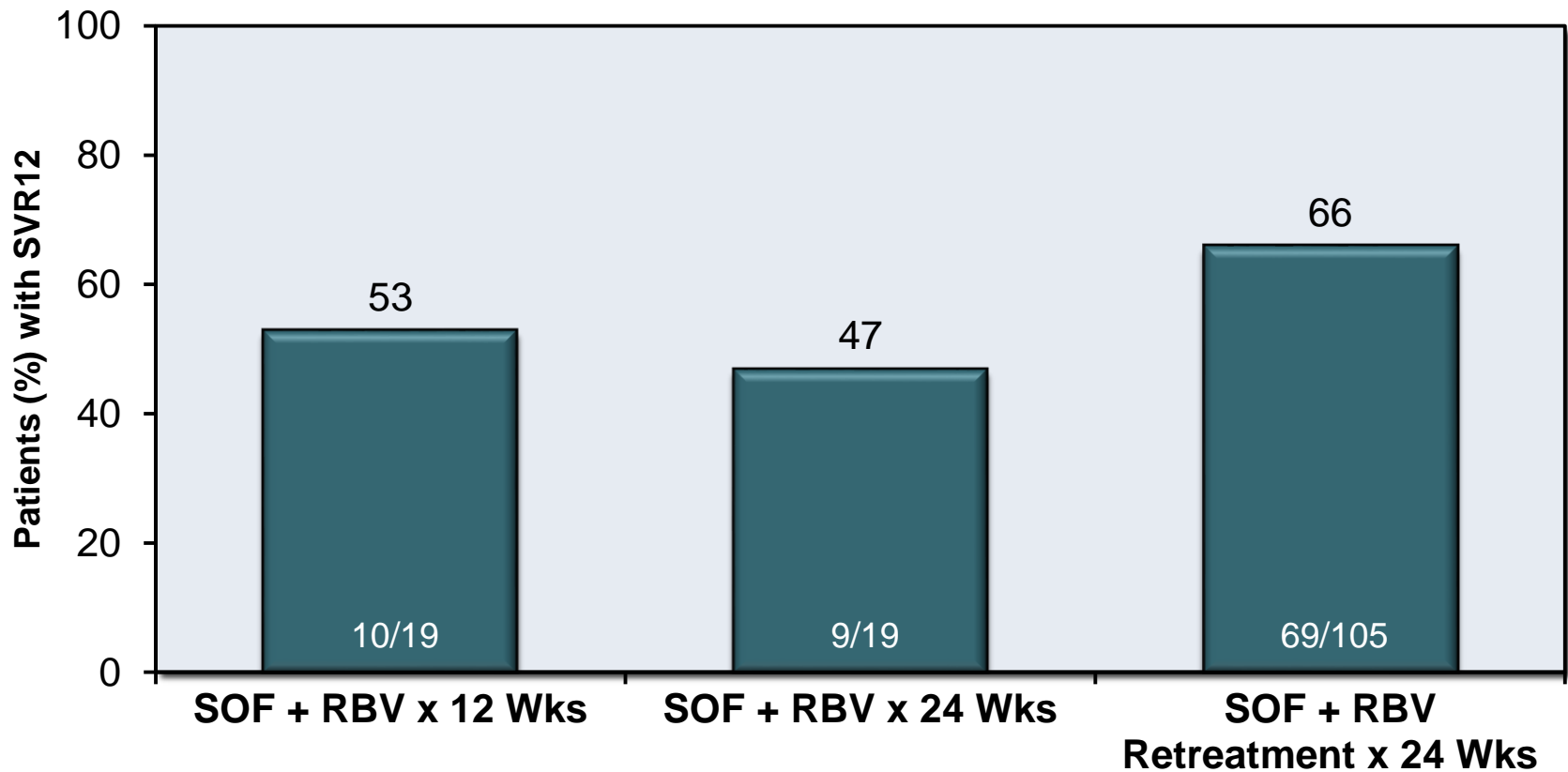


SOF = sofosbuvir; RBV = ribavirin

Source: Lalezari JP, et al. EASL. 2013; Abstract 845.

Sofosbuvir, Ribavirin, & GS-0938 in Treatment Naïve QUANTUM Trial: Results

QUANTUM: SVR12 Results for Patients with Genotype 1

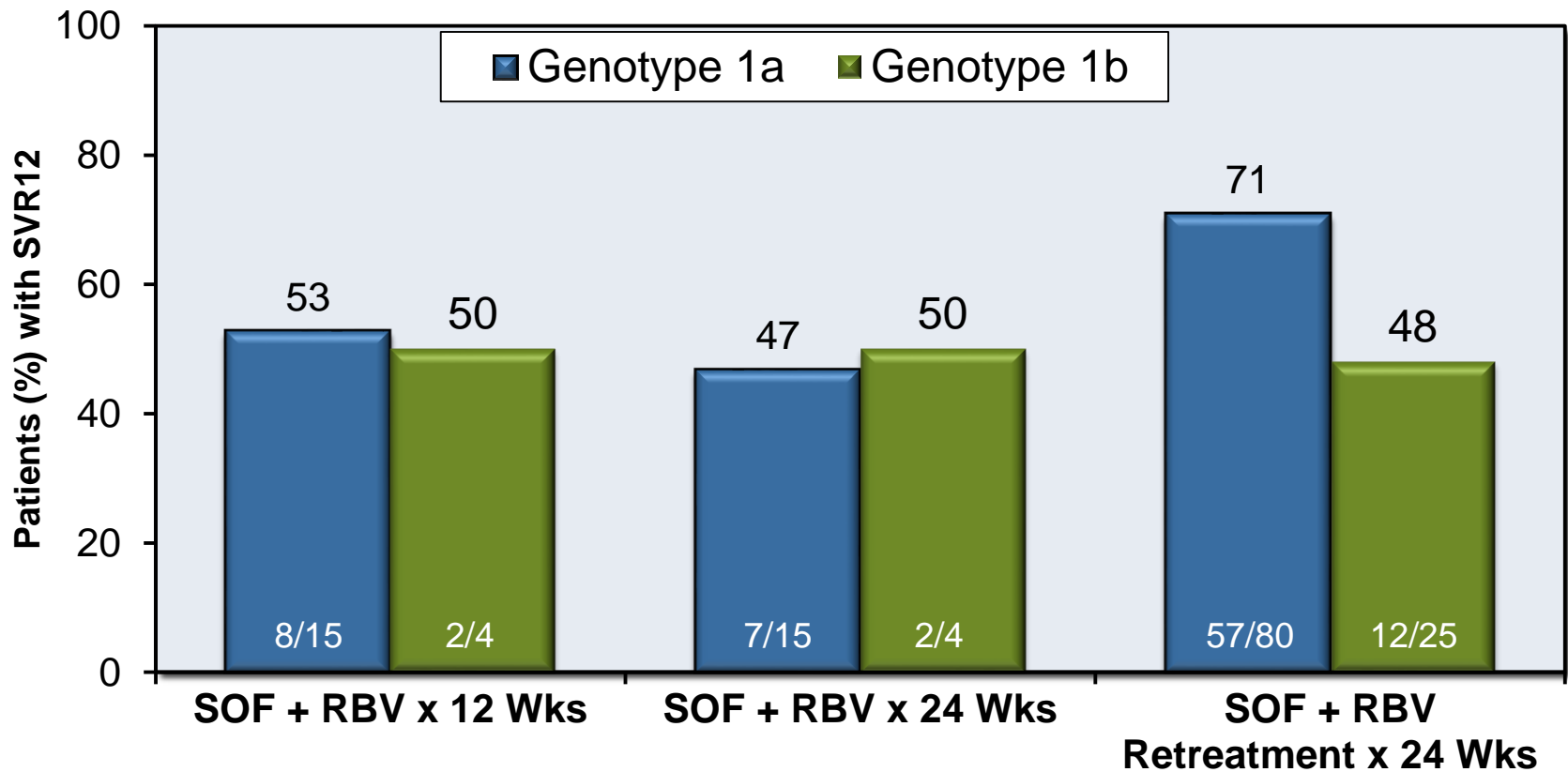


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QUANTUM: SVR12 Results for Patients with Genotype 1



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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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