

Treatment Naïve

Sofosbuvir + Ribavirin + Peginterferon in Genotypes 1-3 PROTON

Lawitz E, et al. Lancet Infect Dis. 2013;13:401-8.

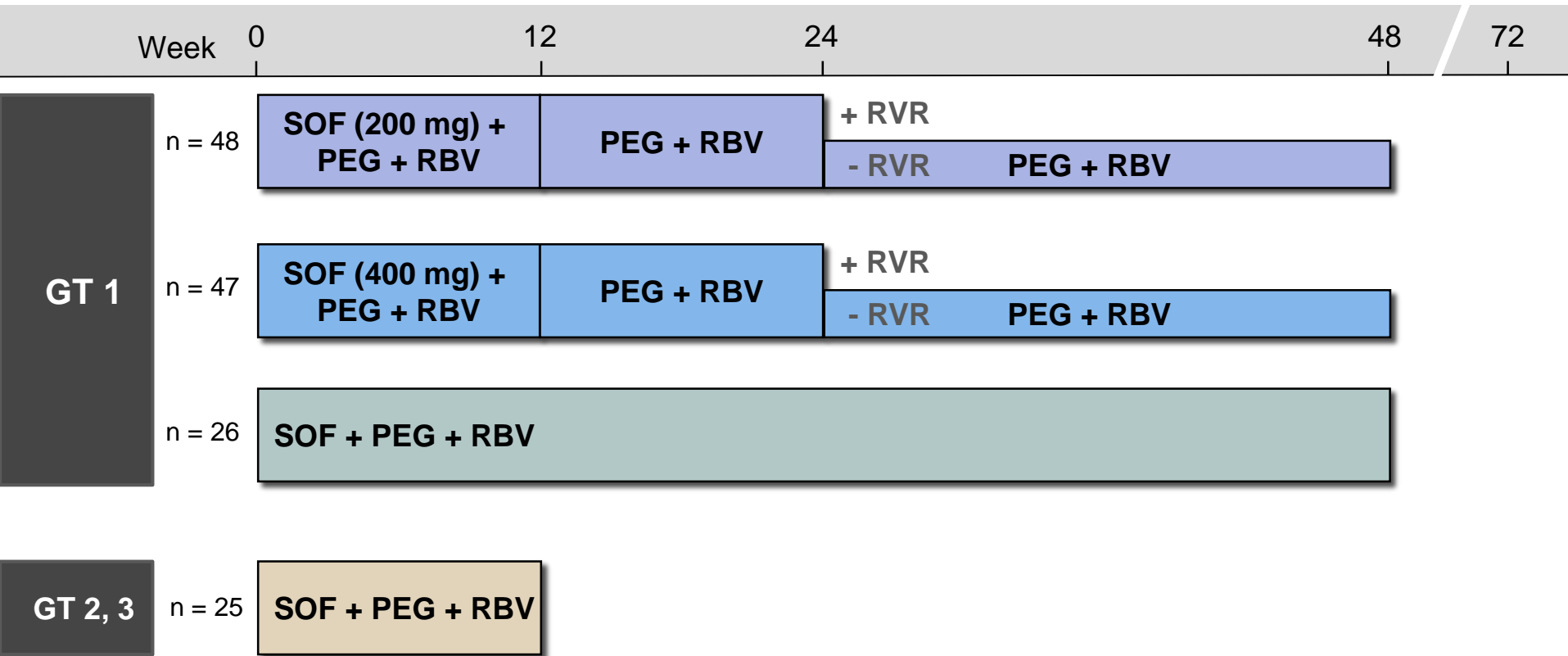
Sofosbuvir + Ribavirin + Peginterferon in Genotypes 1-3

PROTON Trial: Design

PROTON Trial: Features

- **Design:** Randomized, two-cohort, phase 2 trial investigating effectiveness of sofosbuvir, ribavirin, and peginterferon in treatment-naïve GT 1-3
- **Setting:** 22 hepatitis C treatment centers in the United States
- **Entry Criteria**
 - Treatment-naïve
 - HCV RNA RNA \geq 50,000 IU/mL
 - Absence of cirrhosis
- **Patient Characteristics**
 - GT-1 = 121; GT 2= 15; GT 3 = 10
- **Study Arms**
 - Cohort A: GT1; three arms and included 2 doses of sofosbuvir
 - Cohort B: GT 2 or 3
- **Primary End-Point:** SVR24

Sofosbuvir + Peginterferon + Ribavirin in Genotypes 1-3 PROTON Trial: Design



Drug Dosing

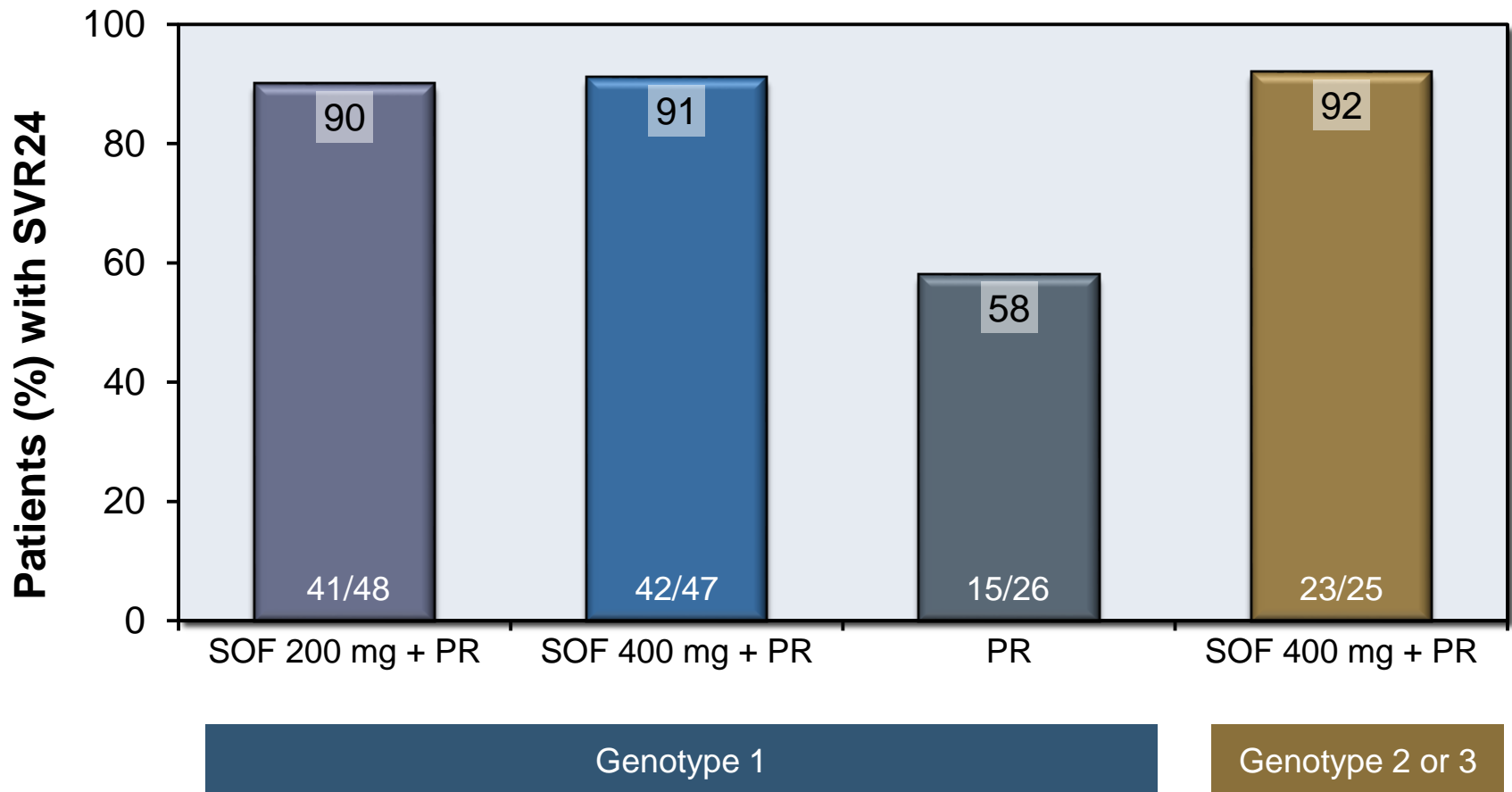
Sofosbuvir (SOF): 400 mg once daily, except as designated in arm that received 200 mg once daily

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

Peginterferon alfa-2a (PEG): 180 µg once weekly

Sofosbuvir + Ribavirin + Peginterferon in Genotypes 1-3 PROTON Trial: Results, by Genotype

PROTON: SVR 24



Sofosbuvir + Ribavirin + Peginterferon in Genotypes 1-3 PROTON Trial: Conclusions

Interpretation: “Our findings lend support to the further assessment, in phase 2 and 3 trials, of sofosbuvir 400 mg plus peginterferon and ribavirin for 12 weeks in treatment-naive patients with HCV genotype-1.”

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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