

Treatment Naïve

Boceprevir with PEG + RBV in Genotype 1 SPRINT-1

Kwo PY, et al. Lancet. 2010;376:705-16.

Boceprevir for Treatment-Naïve HCV Genotype 1

SPRINT-1 Trial: Part 1

SPRINT-1: Features

- N = 520 HCV-monoinfected patients
- Randomized, open label, phase 2 trial, with Part 1 and Part 2
- All with chronic HCV genotype 1 and treatment naïve
- Eligible if 18 to 60 years of age
- Setting: 67 sites (US, Canada, and Europe)
- 90% with HCV RNA $\geq$ 600,000 IU/ml
- Part 1 (n = 520): Randomized to one of five arms
- Part 2 (n = 75): Randomized to one of two arms based on ribavirin dose

Drug Dosing

Boceprevir = 800 mg three times daily

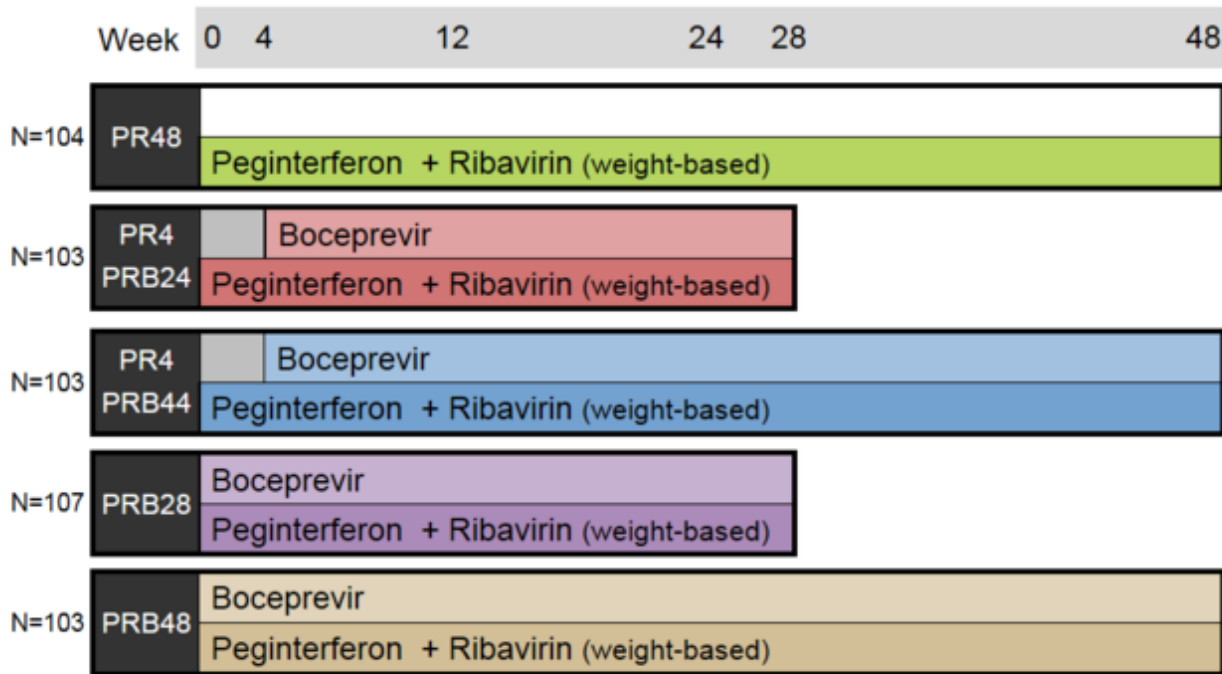
Peginterferon alfa-2b = 1.5 μ g/kg once weekly

Ribavirin = 800-1400 mg/day (based on weight)

Ribavirin = 400-1000 mg/day (low dose)

Boceprevir for Treatment-Naïve HCV Genotype 1

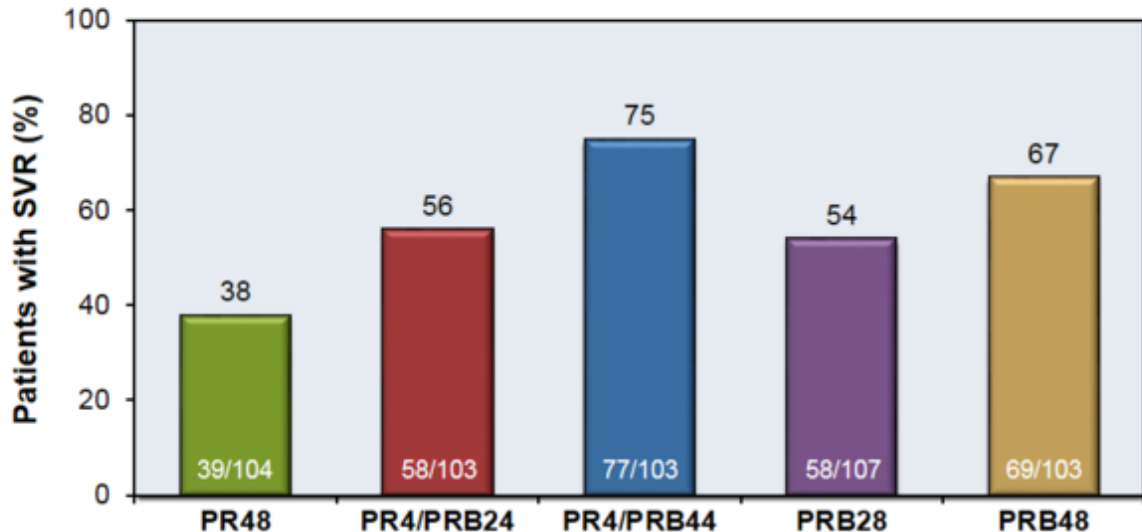
SPRINT-1 Trial, Part 1: Design



Boceprevir for Treatment-Naïve HCV Genotype 1

SPRINT-1 Trial, Part 1: Results

SPRINT-1, Part 1: SVR 24 by Regimen



B = Boceprevir; PR = Peginterferon + Ribavirin

Source: Kwo PY, et al. *Lancet*. 2010;376:705-16.

Boceprevir and Peginterferon plus Ribavirin for Chronic HCV

SPRINT-1 Trial, Part 2: Design

Week 0 12 24 48

N=16

PRB48

Boceprevir

Peginterferon + Ribavirin (weight based)

N=59

Low-Dose

PRB48

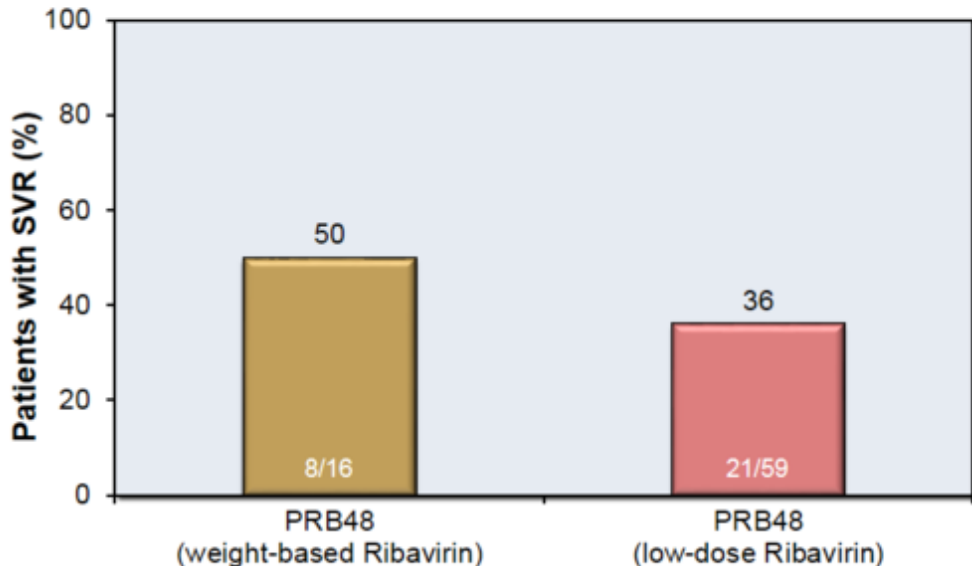
Boceprevir

Peginterferon + Low-Dose Ribavirin (low dose)

Boceprevir and Peginterferon plus Ribavirin for Chronic HCV

SPRINT-1 Trial, Part 2,: Results

SPRINT-1: SVR 24 by Ribavirin Dosing



P = Peginterferon; R = Ribavirin; B = Boceprevir

Source: Kwo PY, et al. *Lancet*. 2010;376:705-16.

Boceprevir and Peginterferon plus Ribavirin for Chronic HCV SPRINT-1 Trial: Conclusions

Interpretation: “In patients with untreated genotype 1 chronic hepatitis C infection, the addition of the direct-acting antiviral agent boceprevir to standard treatment with peginterferon and ribavirin after a 4-week lead-in seems to have the potential to double the sustained response rate compared with that recorded with standard treatment alone.”