Treatment Experienced

Boceprevir in Treatment Experienced
RESPOND-2

Boceprevir for Retreatment of HCV Genotype 1 Infection
RESPOND-2 Trial: Study Design

RESPOND-2: Study Features

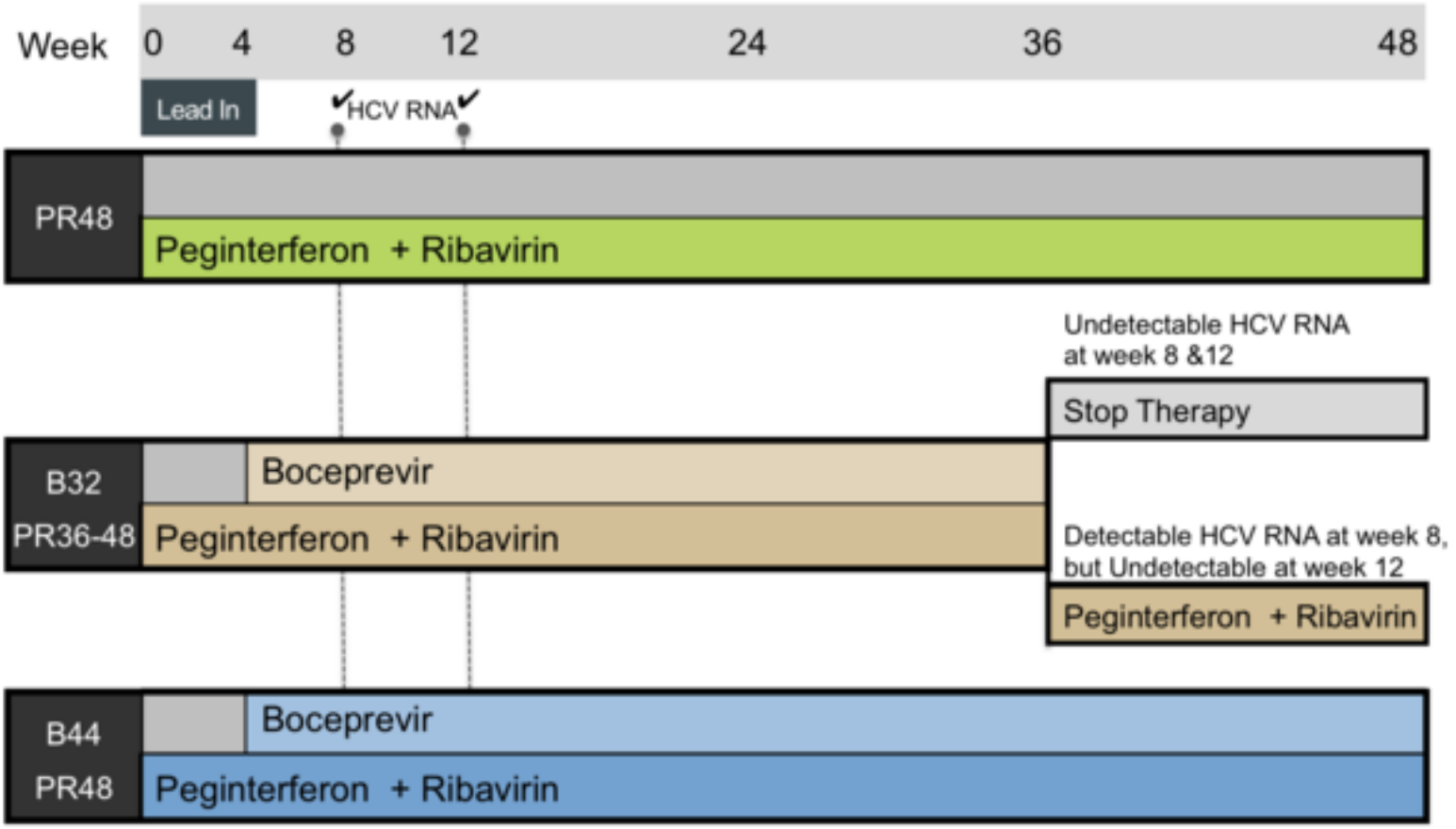
- N = 403 HCV-monoinfected, treatment-experienced patients
- Randomized, double-blind, placebo-controlled, phase 3 study
- All with chronic HCV and genotype 1
- Previously responded to treatment but did not obtain SVR
- Previous *null responders* excluded
- HCV RNA $\geq$ 10,000 IU/ml
- Phase III trial
- Age $\geq$ 18
- Randomized to 3 arms (1:2:2)

Drug Dosing

Boceprevir = 800 mg three times daily
Peginterferon alfa-2b = 1.5 µg/kg once weekly
Ribavirin = 600-1400 mg/day (based on weight)

Source: Bacon BR, et al. N Engl J Med. 2011;364:1207-17.

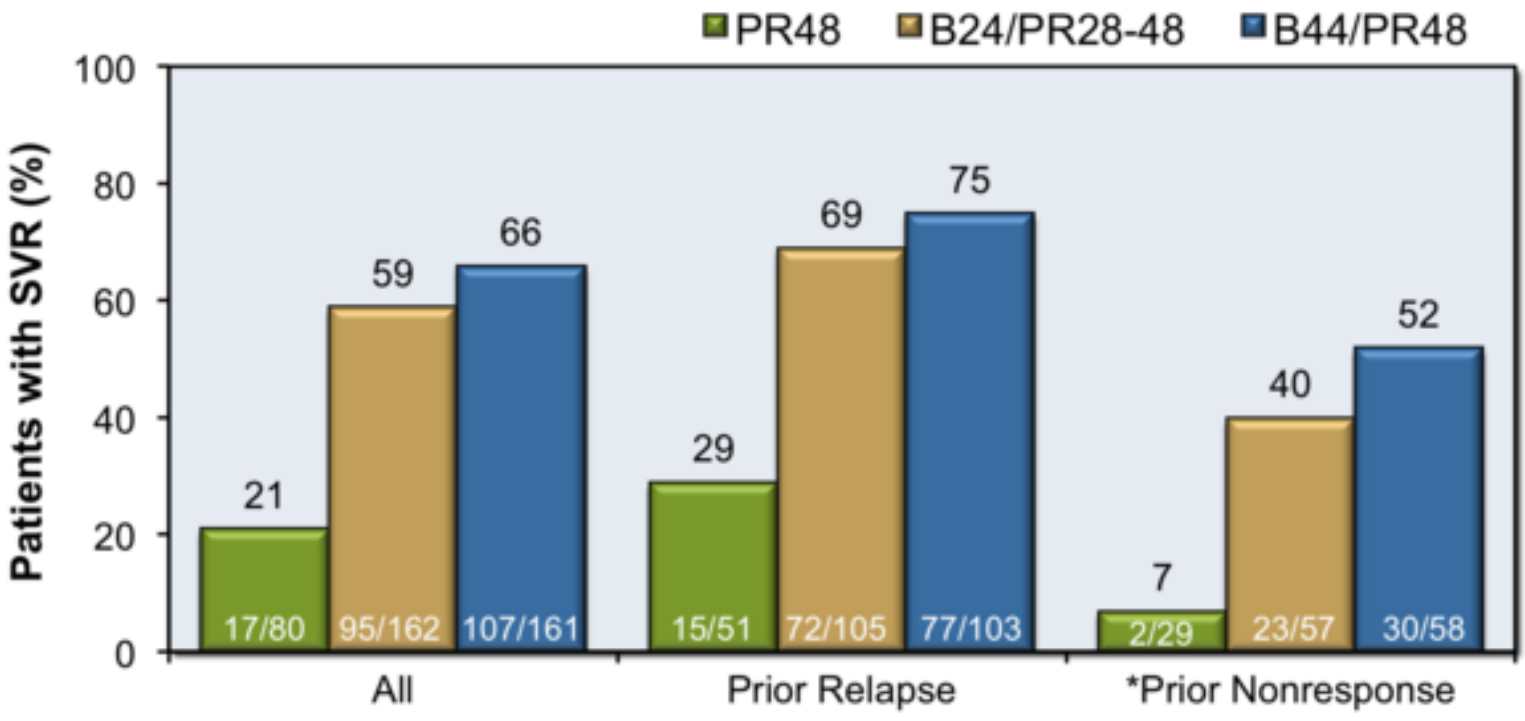
Boceprevir for Retreatment of HCV Genotype 1 Infection
RESPOND-2 Trial: Treatment Regimens



Source: Bacon BR, et al. N Engl J Med. 2011;364:1207-17.

Boceprevir for Retreatment of HCV Genotype 1 Infection
RESPOND-2 Trial: Results

RESPOND-2: SVR 24 by Prior Response and Regimen



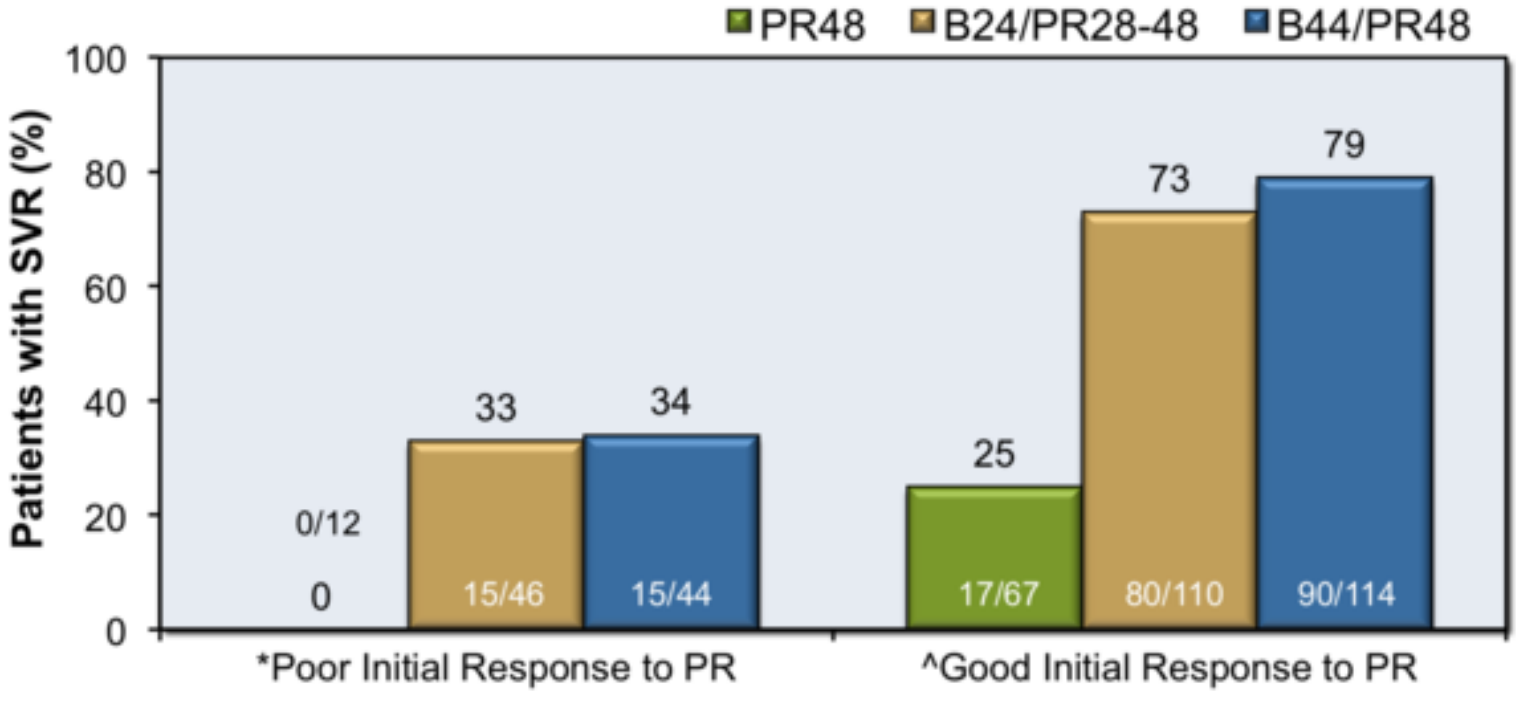
*Prior Nonresponse = decrease in HCV RNA of at least 2 logs by week 12, but detectable HCV RNA level during therapy period

SVR = Sustained Virologic Response; B = Boceprevir; PR = Peginterferon + Ribavirin

Source: Bacon BR, et al. N Engl J Med. 2011;364:1207-17.

Boceprevir for Retreatment of HCV Genotype 1 Infection
RESPOND-2 Trial: Results Based on Initial Week 4 Response

RESPOND-2: SVR 24, by Initial Response and Regimen



*Poor Initial Response to PR = decrease in HCV RNA level < 1 $\log_{10}$ IU/ml after 4 week lead in
^Good Initial Response to PR = decrease in HCV RNA level ≥ 1 $\log_{10}$ IU/ml after 4 week lead in

SVR = Sustained Virologic Response; B = Boceprevir; PR = Peginterferon + Ribavirin

Source: Bacon BR, et al. N Engl J Med. 2011;364:1207-17.

Boceprevir for Retreatment of HCV Genotype 1 Infection
RESPOND-2 Trial: Conclusions

Conclusions: "The addition of boceprevir to peginterferon–ribavirin resulted in significantly higher rates of sustained virologic response in previously treated patients with chronic HCV genotype 1 infection, as compared with peginterferon–ribavirin alone."

Source: Bacon BR, et al. N Engl J Med. 2011;364:1207-17.