



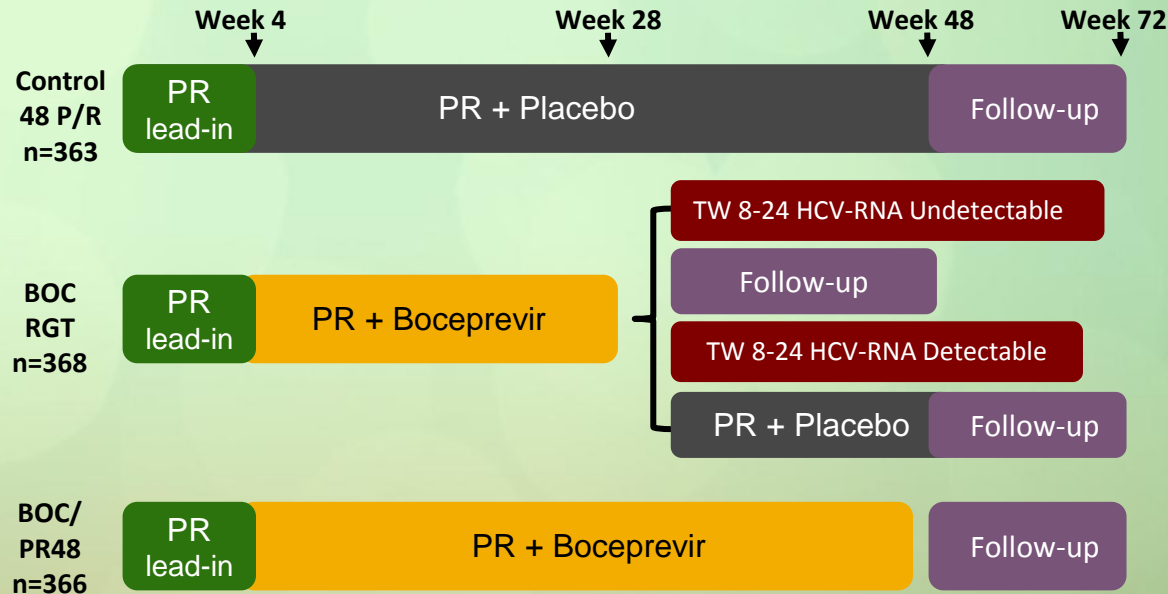
**Boceprevir (BOC) Combined with Peginterferon  
alfa-2b/Ribavirin (P/R) for Treatment-Naïve Patients  
with Hepatitis C Virus (HCV) Genotype (G)  
1: SPRINT-2 Final Results**

**F. Poordad; J. McCone; B. R. Bacon; *et al.***

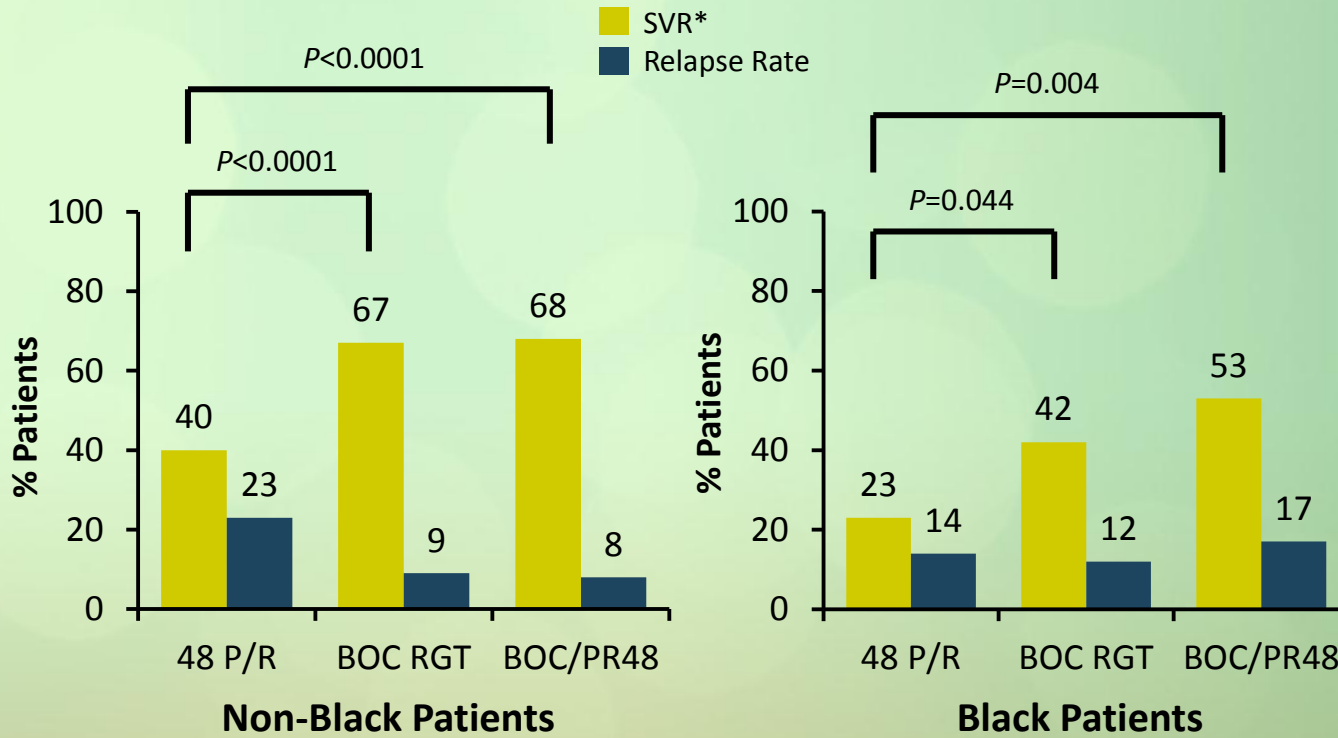
**61st AASLD - Abstract LB-4**

# SPRINT-2: Study Design

- Study to compare safety/efficacy of two treatment strategies with boceprevir added to peginterferon/ribavirin (PR) versus PR alone in treatment naïve HCV genotype 1 patients

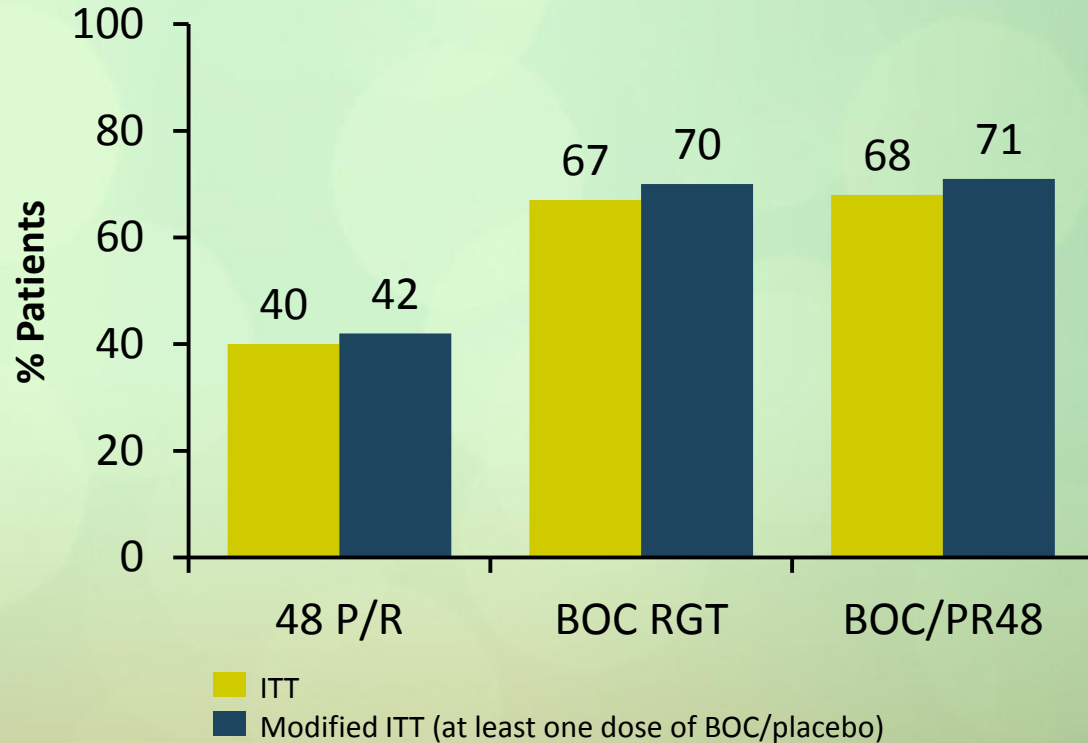


# SPRINT-2: SVR and Relapse Rates (ITT)

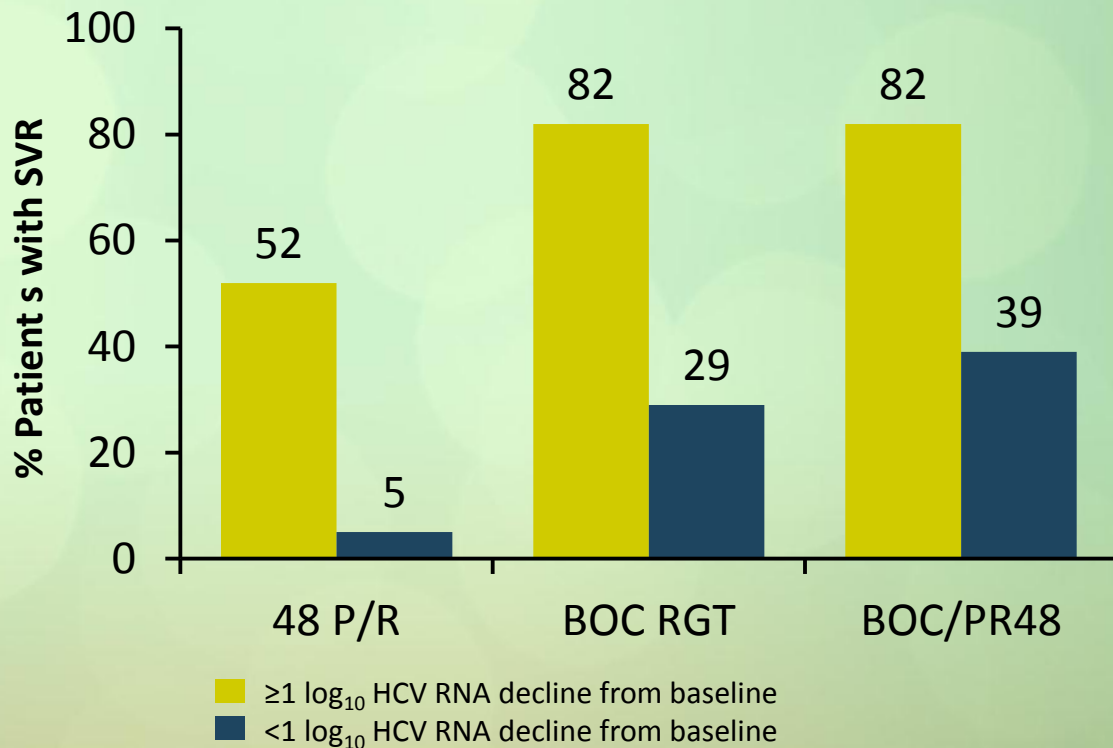


\*SVR was defined as undetectable HCV RNA at the end of the follow-up period.

# SPRINT-2: SVR Rates in Non-Black Patients



# SPRINT-2: SVR Based on Week 4 PR Lead-In in Non-Black Patients



# SPRINT-2: SVR Based on Week 4 PR Lead-In in Non-Black Patients

% Patient s with SVR

Boceprevir Resistance-associated Variants:

≥ 1 log<sub>10</sub> decline:

BOC RGT: 4% (9/232)

BOC/PR48: 4% (9/231)

< 1 log<sub>10</sub> decline:

BOC RGT: 47% (45/95)

BOC/PR48: 35% (33/94)

48 P/R

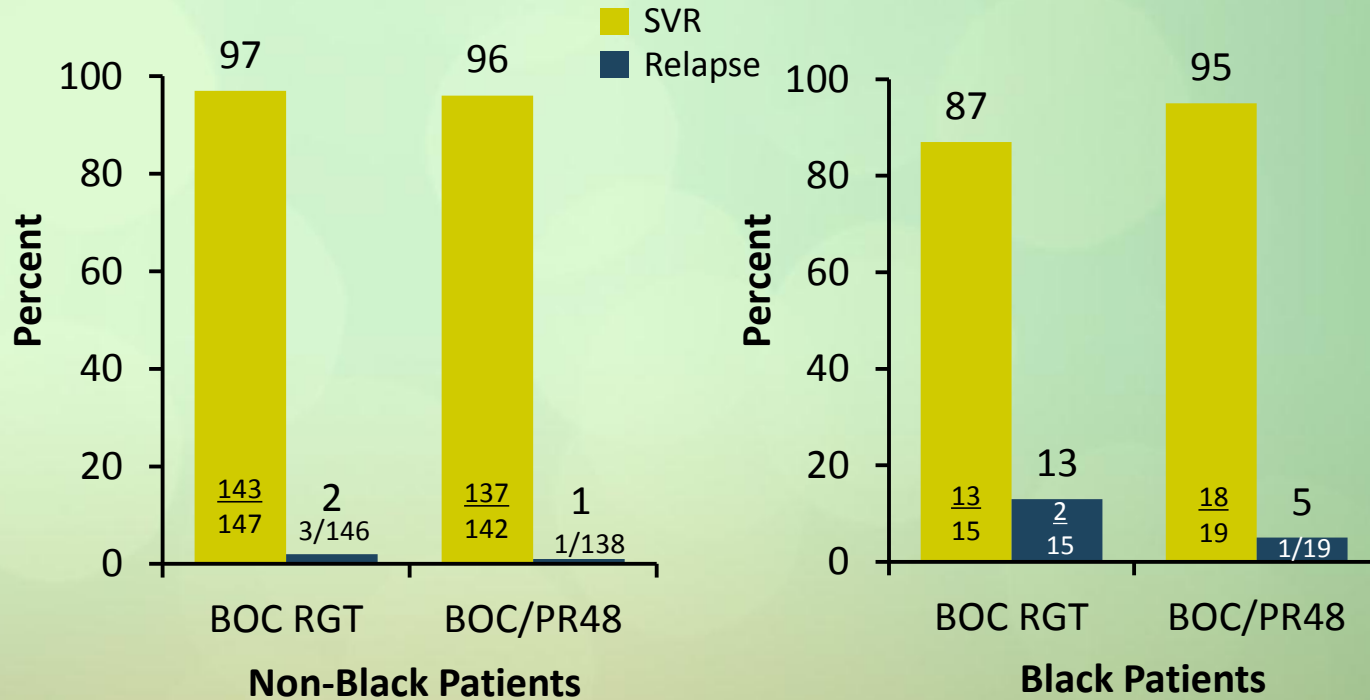
BOC RGT

BOC/PR48

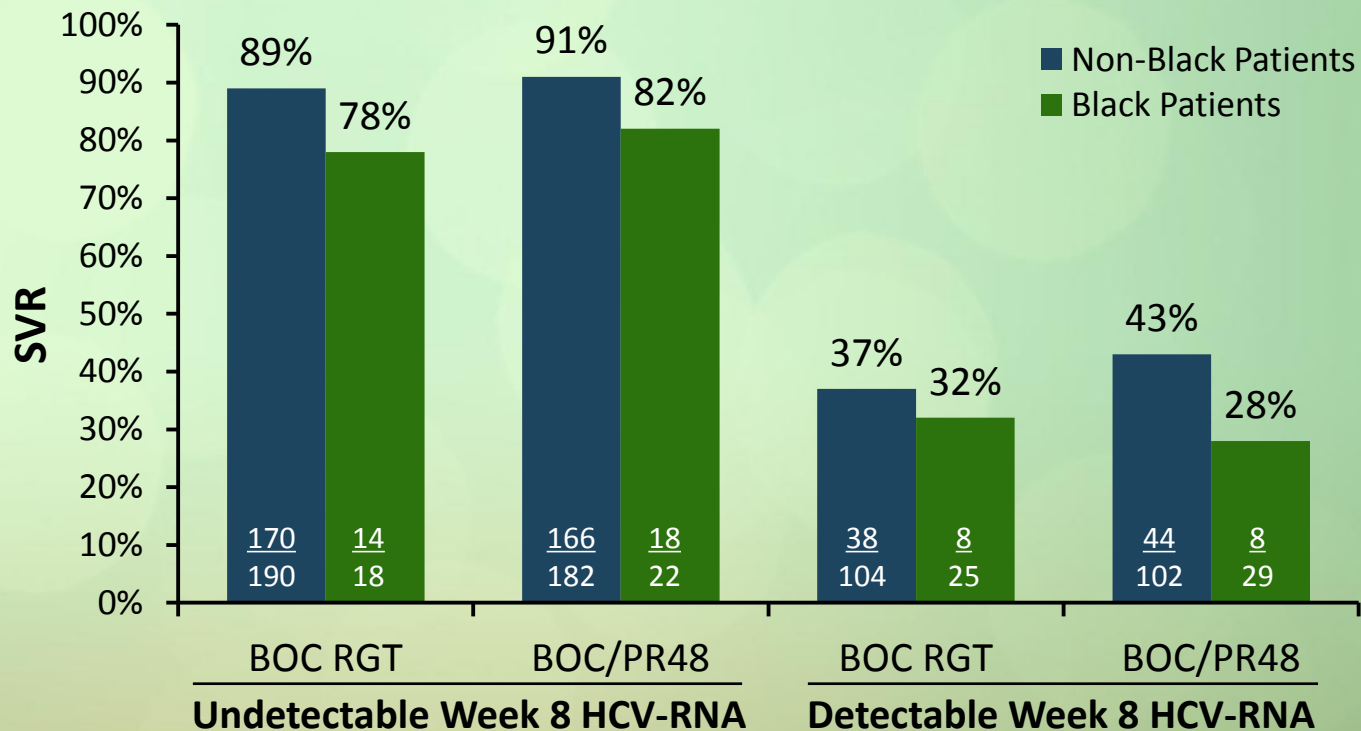
■ ≥1 log<sub>10</sub> HCV RNA decline from baseline

■ <1 log<sub>10</sub> HCV RNA decline from baseline

# SPRINT-2: Virologic Response Rates for Undetectable HCV RNA Levels Weeks 8 to 24



# SPRINT-2: SVR Rates Based on Week 8 HCV RNA





# SPRINT-2: Safety Profile Over Entire Course of Therapy

|   | 48 PR<br>n=363 | BOC RGT<br>n=368 | BOC/PR48<br>n=366 |
|---|----------------|------------------|-------------------|
| Median treatment duration (days)  | 203            | 197              | 335               |
| Deaths (N)  | 4              | 1                | 1                 |
| Serious AEs   | 9%             | 11%              | 12%               |
| Discontinued due to Aes   | 16%            | 12%              | 16%               |
| Dose modification due to AEs  | 26%            | 40%              | 35%               |
| <b>Hematologic parameters</b>   |                |                  |                   |
| Neutrophil count<br>(<750 to 500/mm <sup>3</sup> / <500/mm <sup>3</sup> ) | 14% / 4%       | 24% / 6%         | 25% / 8%          |
| Hemoglobin (<10 to 8.5 g/dL / <8.5 g/dL)                                  | 26% / 4%       | 45% / 5%         | 41% / 9%          |
| Discontinuation due to anemia   | 1%             | 2%               | 2%                |
| Dose reductions due to anemia   | 13%            | 20%              | 21%               |
| Erythropoietin use  | 24%            | 43%              | 43%               |
| Mean (median) days of use   | 121 (109)      | 94 (85)          | 156 (149)         |

# SPRINT-2: Most Common Treatment-Related Adverse Events

| Adverse Event          | Arm 1 (PR48); n=363 (%) | Arm 2 (RGT); n=368 (%) | Arm 3 (BOC/PR48); n=366 (%) |
|------------------------|-------------------------|------------------------|-----------------------------|
| Fatigue                | 59                      | 52                     | 57                          |
| Headache               | 42                      | 45                     | 43                          |
| Nausea                 | 40                      | 46                     | 42                          |
| Anemia                 | 29                      | 49                     | 49                          |
| Dysgeusia              | 18                      | 37                     | 43                          |
| Chills                 | 28                      | 36                     | 33                          |
| Pyrexia                | 32                      | 33                     | 30                          |
| Insomnia               | 32                      | 31                     | 32                          |
| Alopecia               | 27                      | 20                     | 28                          |
| Decreased Appetite     | 25                      | 26                     | 24                          |
| Pruritis               | 26                      | 23                     | 25                          |
| Neutropenia            | 21                      | 25                     | 25                          |
| Influenza Like Illness | 25                      | 23                     | 22                          |
| Myalgia                | 26                      | 21                     | 24                          |
| Rash                   | 22                      | 24                     | 23                          |
| Irritability           | 24                      | 22                     | 22                          |
| Depression             | 21                      | 23                     | 19                          |
| Diarrhea               | 19                      | 19                     | 23                          |
| Dry Skin               | 18                      | 18                     | 22                          |
| Dyspnea                | 16                      | 18                     | 22                          |
| Dizziness              | 15                      | 21                     | 17                          |