**Poster #933**

**Hemoglobin Decline During Lead-in Phase as an Early Predictor of Anemia After the Addition of Boceprevir: A Retrospective Analysis of HCV SPRINT-1**


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**Abstract**

**Background.** SPRINT-1 was a Phase 2b trial of 595 treatment-naive patients to assess the safety and efficacy of a 16-week regimen of peginterferon alfa-2b plus ribavirin (P/R) plus 800 mg boceprevir (BOC) over 48 weeks. The study was designed to be non-inferior to the IDEAL study (P/R treatment alone).

**Methods.** Percentages were compared using χ2 and Fisher’s exact tests; Student’s t-test was used to compare means. Predictive value of hemoglobin (Hb) decline was assessed with the chi-square test. Statistical analysis was performed using SAS software. Hb nadirs were compared in both study arms that incorporated a 4-week, lead-in phase, and in patients who initiated BOC therapy after 4 weeks of P/R treatment. Table 1 shows patients’ demographic and virologic characteristics. Table 2 shows the magnitude of Hb decline during the lead-in and treatment periods. The SPRINT-1 study is registered with ClinicalTrials.gov, number NCT00423670.

**Results.** Median baseline Hb was 12.9 g/dL (range 10.0–17.1), and 27% (163/595) patients had Hb <10 g/dL at baseline. Over the full duration of treatment, nadir Hb <9.5 g/dL was observed in 27% to 29% of patients, regardless of total treatment duration (Hb nadir: treatment weeks [TW] 8, 24, 48).

- Table 1: Results of the SPRINT-1 study. **Table 2:** Patient demographic and virologic characteristics. **Figure 1:** Lead-in phase. **Figure 2:** Hemoglobin decline during lead-in and treatment periods. **Figure 3:** Nadir Hb levels. **Figure 4:** Association between percentage Hb decline at end of lead-in phase and nadir Hb levels during therapy with boceprevir plus P/R at end of phase. **Figure 5:** Association between percentage Hb decline at end of lead-in and nadir Hb levels during therapy with boceprevir plus P/R at end of phase. **Figure 6:** Association between Hb decline and loss of HCV.