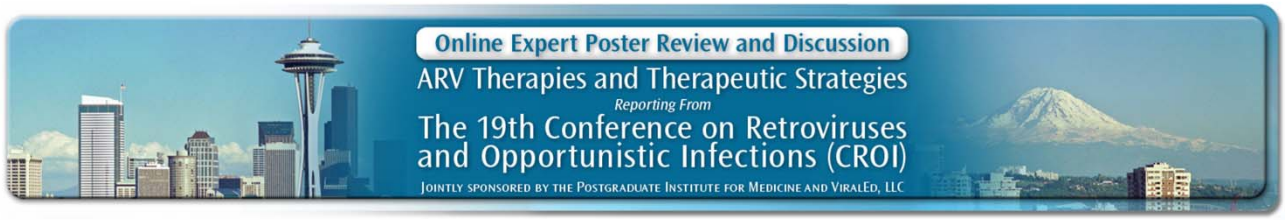

Boceprevir Plus Peginterferon/Ribavirin for the Treatment of HCV/HIV Co-Infected Patients

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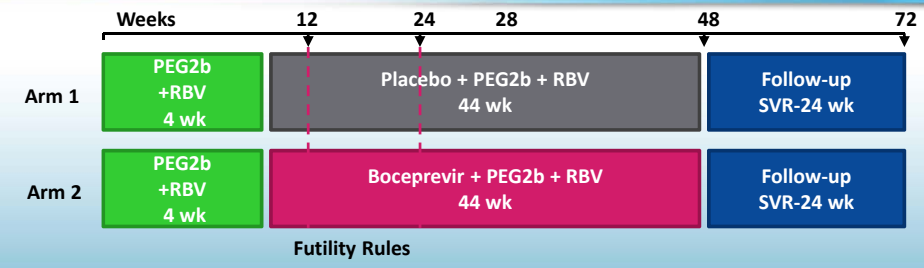
Abstract #47

Study Design



- Two-arm study, double-blinded for BOC, open-label for PEG2b/RBV
  - 2:1 randomization (experimental: control)
  - Boceprevir dose 800 mg TID
- 4-week lead-in with PEG2b/RBV for all patients
  - PEG-2b 1.5 µg/kg QW; RBV 600-1400 mg/day divided BID
- Control arm patients with HCV-RNA ≥ LLOQ at TW 24 were offered open-label PEG2b/RBV+BOC via a crossover arm

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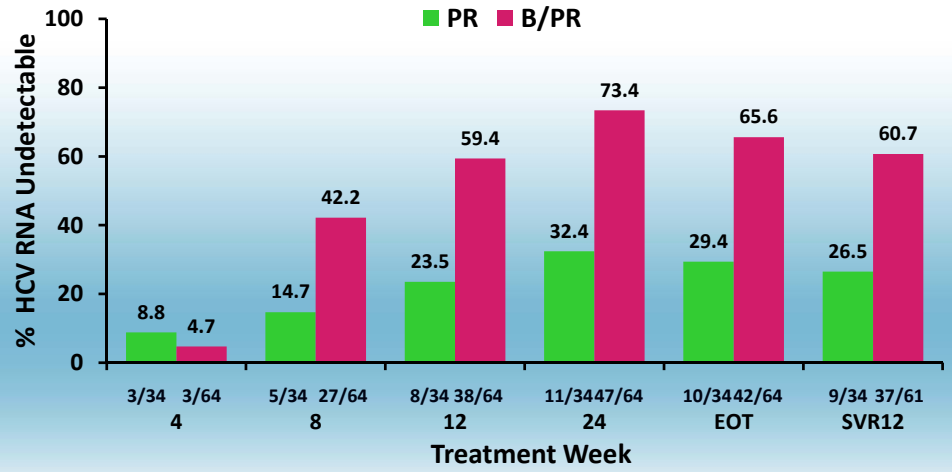
Virologic Response Over Time†



† Three patients undetectable at FW4 have not yet reached FW12 and were not included in SVR12 analysis.

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Most Common Adverse Events With a Difference of ≥10% Between Groups

	PR (N=34)	B/PR (N=64)
Anemia	26%	41%
Pyrexia	21%	36%
Asthenia	24%	34%
Decreased appetite	18%	34%
Diarrhea	18%	28%
Dysgeusia	15%	28%
Vomiting	15%	28%
Flu-like illness	38%	25%
Neutropenia	6%	19%

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Hematologic Adverse Events

	PR (N=34)	B/PR (n=64)
Anemia		
SAEs	6%	3%
AEs leading to discontinuation	3%	2%
WHO, Grade 1-4 (<11.0 g/dL)	53%	63%
Grade 3-4 (<8.0 g/dL)	3%	5%
Erythropoietin use	21%	38%
Transfusions	6%	6%
Neutropenia		
WHO, Grade 1-4 (≤1.5x10^9/L)	74%	86%
Grade 3-4 (<0.75x10^9/L)	12%	27%

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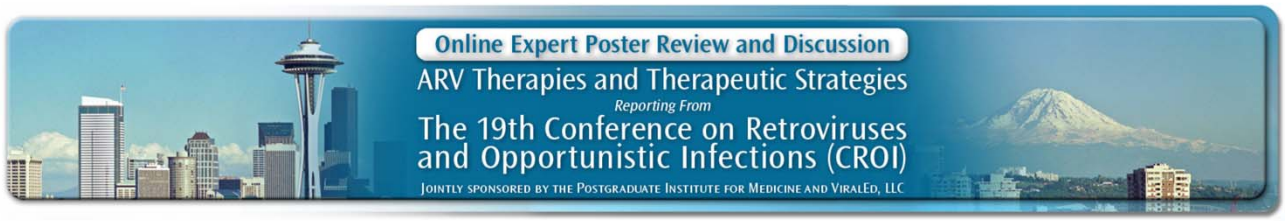


Telaprevir in Combination with Peginterferon Alfa-2a/Ribavirin inHCV/HIV Co-infected Patients: SVR12 Interim Analysis

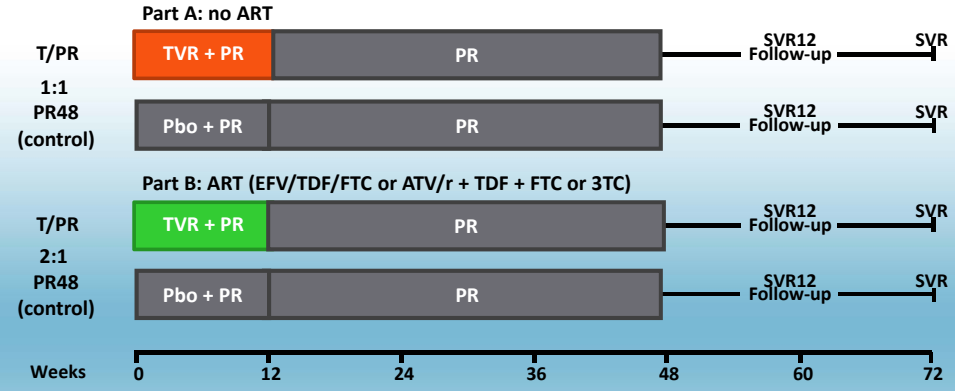
Douglas T. Dieterich[1], Vincent Soriano[2], Kenneth E. Sherman[3], Pierre-Marie Girard[4], Jürgen K. Rockstroh[5], Joshua Henshaw[6], Raymond Rubin[6], Mohammad Bsharat[6], Nathalie Adda6, Mark S. Sulkowski[7]

On behalf of the Study 110 Team

[1]Mount Sinai School of Medicine, New York, NY, United States, [2]Hospital Carlos III, Madrid, Spain, [3]University of Cincinnati College of Medicine, Cincinnati, OH, United States, [4]Hôpital St Antoine, Paris, France, [5]University of Bonn, Bonn, Germany, [6]Vertex Pharmaceuticals Incorporated, Cambridge, MA, United States, and [7]Johns Hopkins University School of Medicine, Baltimore, MD, United States.

Abstract #46

Study 110 Design: Randomized, Double-blind, Placebo-controlled Trial



(EFV)=efavirenz; (TDF)=tenofovir; (FTC)=emtricitabine; (ATV/r)=ritonavir-boosted atazanavir; (3TC)=lamivudine;
(T) TVR=telaprevir 750 mg q8h or 1125 mg q8h (with EFV); Pbo=Placebo; (P) Peg-IFN=pegylated interferon alfa-2a (40 kD) 180 µg/wk; (R) RBV=ribavirin 800 mg/day or weight-based (1000 mg/day if weight <75 kg, 1200 mg/day for if weight ≥75 kg; France, Germany, n=5 patients)
Roche COBAS® TaqMan® HCV test v2.0, LLOQ of 25 IU/mL, LOD of <10 IU/mL

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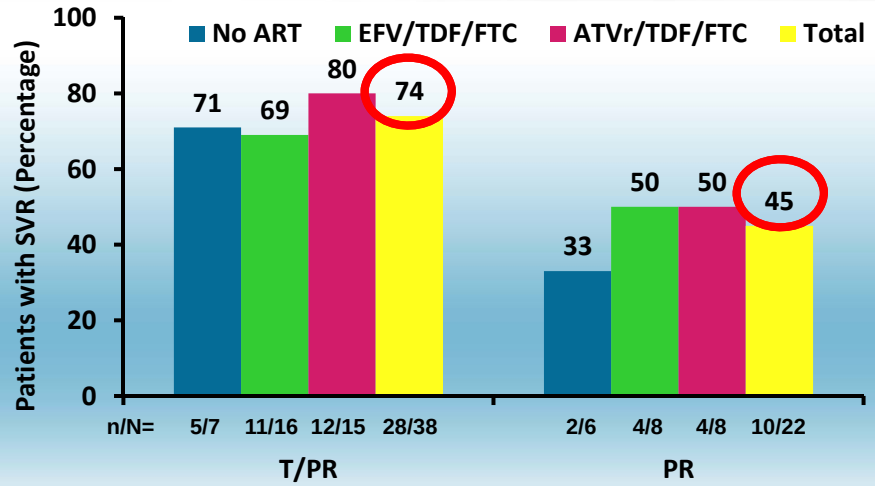
SVR Rates 12 Weeks Post-Treatment (SVR12*)



*Patient was defined as SVR12 if HCV RNA was < LLOQ in the visit window

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Events of Special Interest: Overall Treatment Phase

	T/PR N=38 n (%)	PR N=22 n/N (%)
Severe rash	0 (0)	0 (0)
Mild and moderate rash	13 (34)	5 (23)
Anemia	7 (18)	4 (18)
Grade 3 hemoglobin shifts* (7.0-8.9 g/dL)	11 (29)	5 (23)
Use of erythropoietin stimulating agent	3 (8)	1 (5)
Blood transfusions	4 (11)	1 (5)

- CD4 counts declined in both T/PR and PR groups; CD4% remained unchanged

*DAIDS HIV-negative scale

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