

ONLINE EXPERT POSTER REVIEW AND DISCUSSION

REPORTING FROM

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BOCEPREVIR PLUS PEGINTERFERON/RIBAVIRIN FOR THE TREATMENT OF HCV/HIV CO-INFECTED PATIENTS: END OF TREATMENT (WEEK 48) INTERIM RESULTS

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Abstract #50

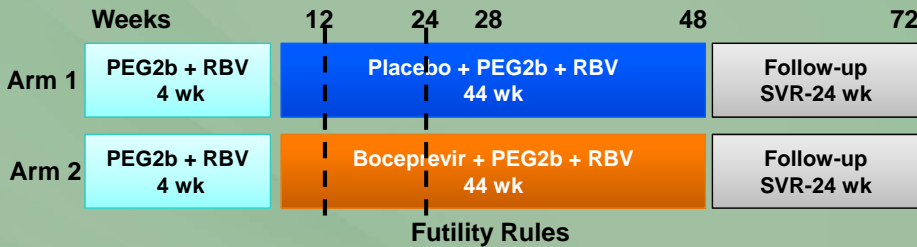
Effect of HCV on disease progression

Results – hazard for HCV status and death

	Pre-cART aHR (95% CI)	cART aHR (95% CI)
HIV/AIDS		
HCV-MSM/MSW/haemophilia	1 (ref)	1 (ref)
HCV+MSM	0.70 (0.42-1.17)	3.11 (1.49-6.48)
HCV+MSM/haemophilia	0.78 (0.56-1.07)	3.48 (1.70-6.93)
HCV-IDU	1 (ref)	1 (ref)
HCV+IDU	0.55 (0.33-0.90)	2.43 (1.14-5.20)
Hepatitis/Liver		
HCV-MSM/MSW/haemo/IDU	1 (ref)	1 (ref)
HCV+IDU	21.8 (6.26-75.9)	7.86 (2.56-24.1)
HCV+MSM/MSW/haemophilia	27.9 (8.39-92.6)	10.0 (3.14-32.2)

- 9164 HIV seroconverters included 2015 (22%) were HCV coinfectd

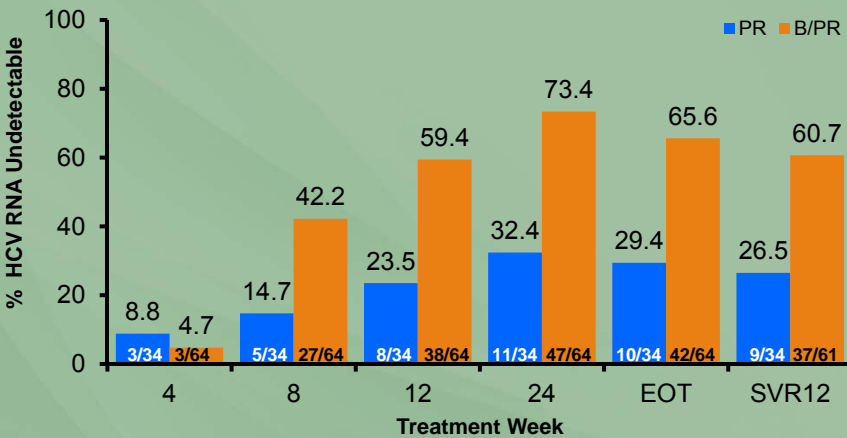
BOC + PEG/RBV for HCV/HIV Co-infection



- 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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BOC: Virologic Response Over Time



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BOC: Most Common Adverse Events With a Difference of $\geq 10\%$ 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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HIV Breakthroughs in B/PR Group

- Overall, 7 patients had HIV breakthrough (>50 copies HIV RNA at 2 consecutive visits): 3/64 randomized to B/PR, and 4/34 to PR

Regimen	HIV RNA (copies/mL)						
	BL	TW4	TW12	TW24	TW36	EOT	FW4
ATV/r	<50	<50	---	659	---	53	2990
LPV/r†	<50	<50	<50	55	59	67	68
ATV/r	<50	<50	<50	<50	243	---	7870

ATV/r, atazanavir/ritonavir; LPV/r, lopinavir/ritonavir
 †The only subject to change ART. LPV/r changed to ATV/r at TW42; ATV/r to DRV/r at FW24.

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Study 110: Telaprevir in HIV/HCV Co-infected Patients

Part A: no ART



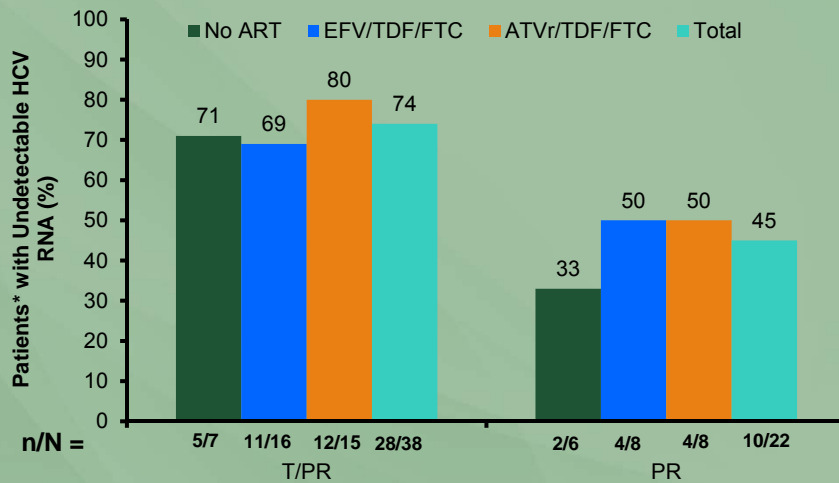
Part B: ART (EFV/TDF/FTC or ATV/r + TDF + FTC or 3TC)



Weeks: 0, 12, 24, 36, 48, 72

Dieterich D, et al. 19th CROI; Seattle, WA; March 5-8, 2012. Abst. 46.

Study 110: SVR Rates 12 Weeks Post-Treatment (SVR12)



Dieterich D, et al. 19th CROI; Seattle, WA; March 5-8, 2012. Abst. 46.

Study 110: Most Common Adverse Events: Overall Treatment Phase

N, (%)	T/PR (N=38), %	PR (N=22), %
Fatigue	16 (42)	9 (41)
Pruritus	15 (39)	2 (9)
Headache	14 (37)	6 (27)
Nausea	13 (34)	5 (23)
Rash	13 (34)	5 (23)
Diarrhea	9 (24)	4 (18)
Dizziness	8 (21)	3 (14)
Pyrexia	8 (21)	2 (9)
Depression	8 (21)	2 (9)
Neutropenia	9 (24)	5 (23)
Anemia [†]	7 (18)	4 (18)
Vomiting	7 (18)	2 (9)
Myalgia	6 (16)	5 (23)
Chills	6 (16)	4 (18)
Insomnia	5 (13)	5 (23)
Decreased Appetite	4 (11)	4 (18)
Weight Decreased	5 (13)	5 (23)

Dieterich D. et al. 19th CROI, Seattle, WA, March 5-8, 2012. Abst. 46.

HIV/HCV PIs

Telaprevir

	Effect of TVR	Effect on HIV PI
LPV/r	AUC ↓ 54% Cmax ↓ 53% Cmin ↓ 52%	AUC ↑ 6% Cmax ↓ 4% Cmin ↑ 14%
ATV/r	AUC ↓ 20% Cmax ↓ 21% Cmin ↓ 15%	AUC ↑ 17% Cmax ↓ 15% Cmin ↑ 85%
DRV/r	AUC ↓ 35% Cmax ↓ 36% Cmin ↓ 32%	AUC ↓ 40% Cmax ↓ 40% Cmin ↓ 42%

Boceprevir

	Effect of BOC	Effect on HIV PI
LPV/r	AUC ↓ 45% Cmax ↓ 50% Cmin ↓ 57%	AUC ↑ 34% Cmax ↓ 30% Cmin ↑ 43%
ATV/r	AUC ↓ 5% Cmax ↓ 7% Cmin ↓ 18%	AUC ↑ 35% Cmax ↓ 25% Cmin ↑ 49%
DRV/r	AUC ↓ 32% Cmax ↓ 25% Cmin ↓ 35%	AUC ↓ 44% Cmax ↓ 36% Cmin ↓ 59%

van Heeswijk R. et al. CROI 2011. Abstract 119
Hulstoke E. et al. CROI 2012. Abstract 771LB

HIV NNRTIs + HCV PIs

Telaprevir

	Effect of TVR	Effect on HIV PI
LPV/r	AUC ↓ 18% Cmax ↓ 24% Cmin ↓ 10%	AUC ↓ 18% Cmax ↓ 14% Cmin ↓ 25%
ATV/r	AUC ↓ 16% Cmax ↓ 10% Cmin ↓ 25%	AUC ↔ Cmax ↔ Cmin ↔
DRV/r	AUC ↓ 5% Cmax ↓ 3% Cmin ↓ 11%	AUC ↑ 78% Cmax ↑ 49% Cmin ↑ 93%

Boceprevir

	Effect of BOC	Effect on HIV PI
LPV/r	AUC ↓ 19% Cmax ↓ 8% Cmin ↓ 44%	AUC ↑ 20% Cmax ↑ 11%
ATV/r	AUC ↑ 10% Cmax ↑ 10% Cmin ↓ 12%	AUC ↓ 23% Cmax ↓ 24% Cmin ↓ 29%
DRV/r		

*Telaprevir 1125 mg tid

van Heeswijk R, et al. CROI 2011. Abstract 119
Kaserra C, et al. CROI 2011. Abstract 118

Hammond K, et al. IWCPHIV 2012. Abstract O 15
Kakuda T, et al. IWCPHIV 2012. Abstract O 18