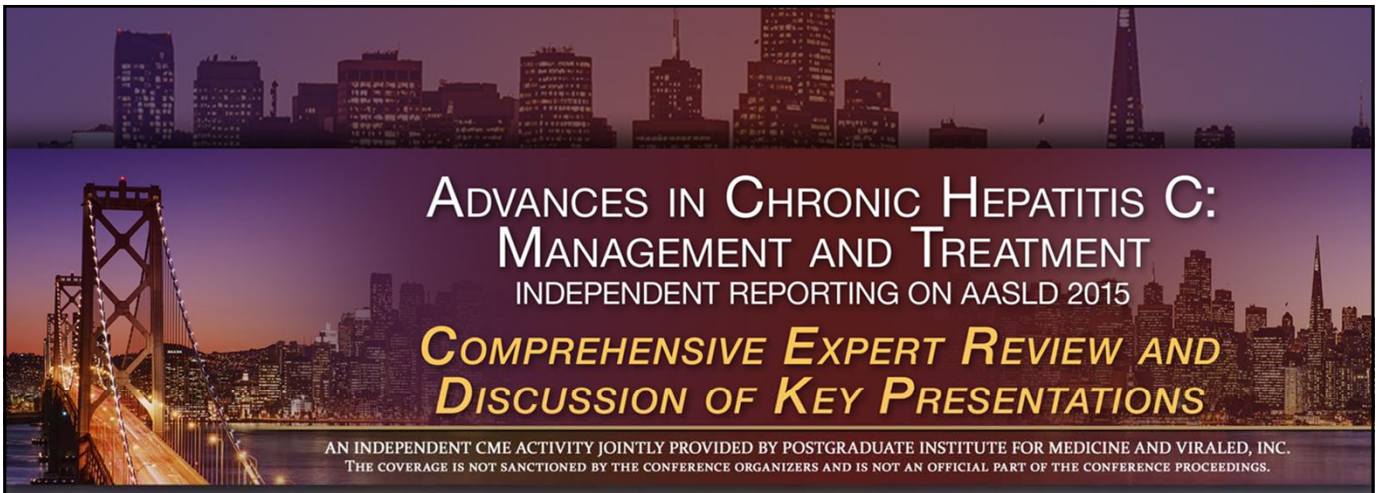


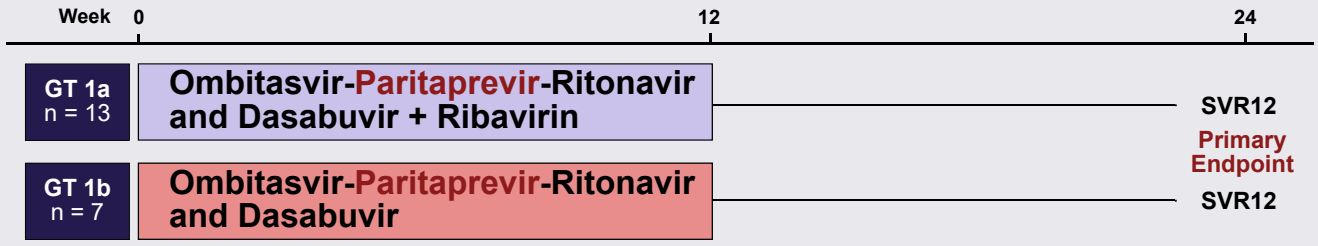
RUBY-I: Ombitasvir/Paritaprevir/Ritonavir + Dasabuvir ± Ribavirin in Non Cirrhotic HCV Genotype 1-Infected Patients with Severe Renal Impairment or End-Stage Renal Disease

Paul J Pockros, K Rajender Reddy, Parvez S Mantry, Eric Cohen, Michael Bennett , Mark S Sulkowski, David Bernstein, Daniel E Cohen, Nancy S Shulman, Deli Wang, Amit Khatri, Manal Abunimeh, Thomas Podsadecki, Eric Lawitz

Abstract 1039

RUBY-I: Study Design

Phase 3b, randomized, open-label trial at 9 US sites evaluating safety and efficacy of 3D (ombitasvir-paritaprevir-ritonavir and dasabuvir) with or without ribavirin for 12 weeks in treatment-naïve patients with chronic HCV GT1* and advanced kidney disease (stage 4 or 5 [eGFR <30 mL/min/1.73 m^2] +/- HD)



Drug Dosing
Ombitasvir-Paritaprevir-Ritonavir (25/150/100 mg once daily) + Dasabuvir: 250 mg twice daily
Ribavirin for patients not on hemodialysis: 200 mg once daily
Ribavirin for patients on hemodialysis: 200 mg given 4 hours before each hemodialysis session

*Plasma HCV RNA greater than 1,000 IU/mL, No cirrhosis or coinfection with HBV or HIV, Baseline Hb ≥10 g/dL

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RUBY-I: Baseline Characteristics

Characteristic	Cohort 1 (N=20)
Male, n (%)	17 (85)
Black, n (%)	14 (70)
Age (years), mean (range)	59.1 (49 - 69)
BMI (kg/m^2), mean (range)	30.1 (20.3 - 37.1)
HCV genotype 1a, n (%)	13 (65)
IL28B non-CC genotype, n (%)	14 (70)
HCV RNA (log_{10} IU/mL), mean ± SD	6.58 ± 0.56
Chronic Kidney Disease (CKD) Stage	
Stage 4	6 (30)
Stage 5	14 (70)
eGFR (mL/min/1.73^2), mean (range)	14.8 (5.4 - 29.9)
Hemoglobin (g/dL), mean (range)	12.5 (9.5 - 16.6)

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RUBY-I: Cohort 1 Efficacy

Subject	1001	1002	1202	1206	1207	1209	1210	1211	1301	1302	1304	1501	1502	1601	1602	1701	1603	1503	1604	1102
GT1a or 1b	1a	1a	1a	1a	1b	1a	1a	1a	1a	1a	1b	1a	1a	1a	1b	1b	1b	1b	1b	1a
Renal Stage 4?	Yes	Yes	No	No	No	No	No	Yes	No	No	No	No	Yes	Yes	No	Yes	No	No	No	No
AGE	56	56	62	60	64	70	63	52	58	60	64	61	49	66	55	65	62	63	58	49
Gender	Male	Female	Male	Male	Male	Male	Male	Male	Female	Male	Male	Male	Female	Male	Male	Male	Male	Male	Male	Male
IL28B	T/T	C/T	C/C	C/C	C/T	C/T	T/T	C/C	C/T	T/T	T/T	C/C	C/C	C/C	C/T	C/T	C/T	C/T	C/T	C/T
Race	- Black or African American	- Black or African American	- White	- White	- Black or African American	- White	- Black or African American	- White	- Black or African American	- Black or African American	- Black or African American	- White	- White	- Black or African American	- Black or African American	- Black or African American	- Black or African American	- Black or African American	- Black or African American	- Black or African American
Ethnicity	None	None	- Hispanic or Latino	- Hispanic or Latino	None	- Hispanic or Latino	None	None	None	None	None	None	None	None	None	None	None	None	None	None
BASE	746000	25300000	17100000	3520000	2980000	429000	1730000	43300000	12600000	6670000	9820000	292000	6980000	2570000	3680000	383000	1230000	6500000	1850000	4210000
W1	25	2310	129	25	152	25	0	311	414	0	625	0	138	25	61	25	25	1090	38	94
W2	0	261	25	0	42	0	25	25	25	25	399	25	25	25	0	0	0	175	0	40
W4	0	25	0	0	0	0	0	0	0	0	25	0	0	0	0	0	0	59	0	0
W8	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
W12EOT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PTW4	0	0	0	0	0	0	0	0	0	Death	0	0	0	0	0	0	0	0	0	146000
PTW12	0	0	0	0	0	0	0	0	0		0	0	0	0	0	0	0	0	0	
PTW24	0	0	0	0	0	0			0											

HCV RNA quantifiable
HCV RNA <25 target detected
HCV RNA <25 target not detected

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RUBY-I: Safety

Cohort 1

- 9 Treatment-emergent SAEs in 4 subjects
  - 1 Death (1302: LV systolic dysfunction/cardiac arrest)
  - 0 DAA drug-related SAEs in 0 subjects
- Grade 3+ ALT elevations: 0
- Discontinuation of DAAs due to AE: 0

Cohort 2

- 0 SAEs in 0 subjects
  - 0 Deaths
  - 0 DAA drug-related SAEs in 0 subjects
- Grade 3+ ALT elevations: 0
- Discontinuation of DAAs due to AE: 0

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