

# ADVANCES IN CHRONIC HEPATITIS C: MANAGEMENT AND TREATMENT

INDEPENDENT REPORTING ON AASLD 2015

## COMPREHENSIVE EXPERT REVIEW AND DISCUSSION OF KEY PRESENTATIONS

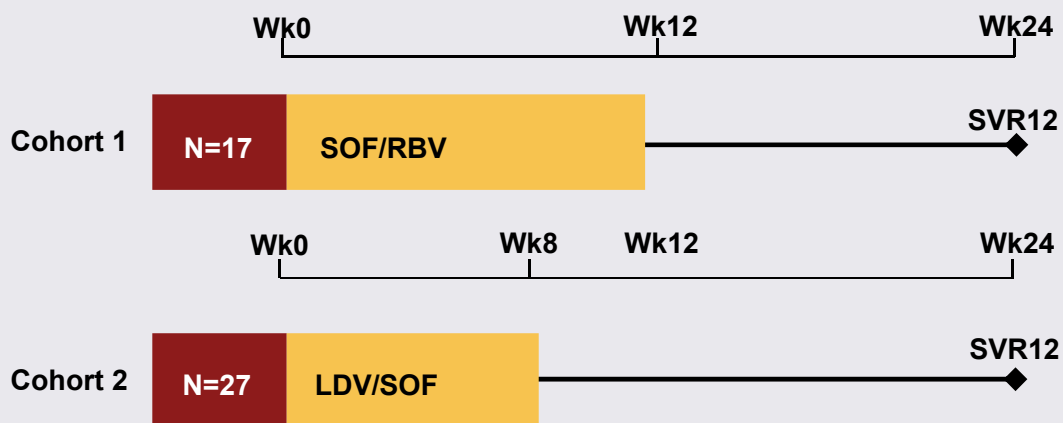
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### Sofosbuvir Plus Ribavirin Without Interferon for Treatment of Acute Hepatitis C Virus Infection in HIV-1 Infected Individuals (SWIFT-C)

Susanna Naggie, Kristen M. Marks, Michael Hughes, Daniel S. Fierer, Arthur Y. Kim, Kimberly Hollabaugh, Jennifer Kiser, Jhoanna Roa, Bill Symonds, Diana M. Brainard, John G. McHutchison, Marion G. Peters, Raymond T. Chung

Abstract 1094

## SWIFT-C: SOF + RBV for Acute HCV in HIV-1 Infected

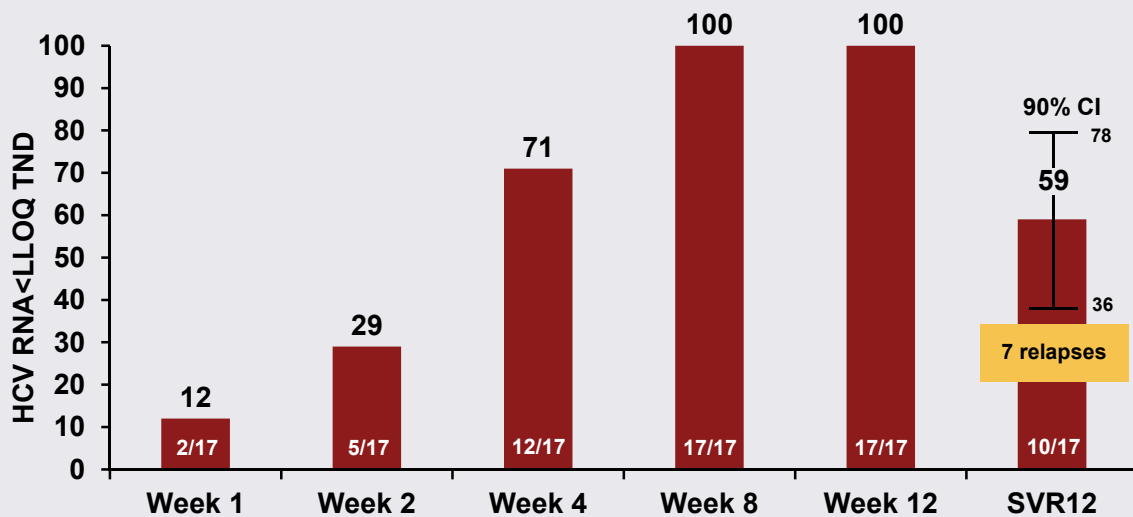


## SWIFT-C: Results - Demographics and Baseline Characteristics

	SOF/RBV - 12 Weeks N=17
Median age, y (quartiles)	45 (41, 47)
Male, n (%)	17 (100)
White, n (%)	6 (35)
Hispanic or Latino, n (%)	11 (65)
IV Drug Use Ever, n (%)	4 (24)
IL28B CC, n (%)	4 (24)
GT 1, n (%)	15 (88)
First HCV infection, n (%)	17 (100)
Mean HCV RNA, log <sub>10</sub> IU/mL ± SD	5.63 ± 1.76
Median time (days) from first evidence of infection (quartiles)	140 (121, 151)
Median CD4, cells/ μL (quartiles)	498 (387, 612)
HIV RNA <50 copies/mL, n (%)	15 (88)
Median ALT, mg/dL (quartiles)	181 (165, 284)
Median AST, mg/dL (quartiles)	106 (69, 159)
Median Tbili, mg/dL (quartiles)	0.70 (0.60, 0.80)

Naggie S, et al. 66th AASLD; San Francisco, CA; November 13-17, 2015; Abst. 1094.

## SWIFT-C: Results - Viral Suppression Rates



Naggie S, et al. 66th AASLD; San Francisco, CA; November 13-17, 2015; Abst. 1094.

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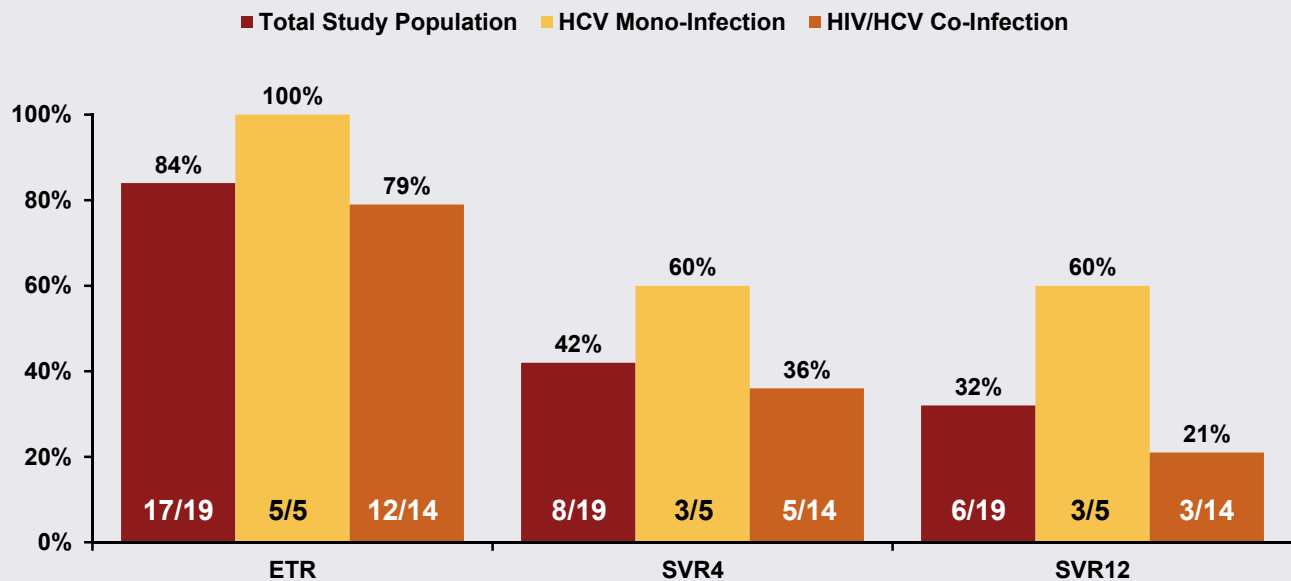
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### Sofosbuvir and Ribavirin for Six Weeks is Not Effective Among People with Acute and Recently Acquired HCV Infection: The DARE-C II Study

Marianne Martinello, Edward J. Gane, Margaret Hellard, Joe Sasadeusz, David Shaw, Kathy Petoumenos, Tanya L. Applegate, Jason Grebely, Laurence Maire, Philippa Marks, David Cooper, Gregory Dore, Gail Matthew

Abstract 1083

## DARE-C II Study: Efficacy Endpoints by HIV Status



Martinello M, et al. 66th AASLD; San Francisco, CA; November 13-17, 2015; Abst. 1083.

## DARE-C II Study: Primary Efficacy Endpoint at Post-Treatment Week 12

Efficacy	Total Study Population (n=19)	Genotype 1 (n=13)	Genotype 2 (n=1)	Genotype 3 (n=5)
SVR 12ITT, n (%)	6 (32)	3 (23)	1 (100)	2 (40)
Failure of Viral Suppression	2 (11)	1 (8)	0	1 (20)
Relapse	9 (47)	8 (62)	0	1 (20)
Reinfection*	1 (5)	0	0	1 (20)
Lost to Follow Up	1 (5)	1 (8)	0	0

\*Reinfection HIV-positive male with recurrence of HCV viraemia between post-treatment weeks 4 and 12. Screening G3a. Week 12 post-treatment. G1a.

Martinello M, et al. 66th AASLD; San Francisco, CA; November 13-17, 2015; Abst. 1083.

## Sofosbuvir and Ledipasvir vs Sofosbuvir and Simeprevir Combination Therapy in the Management of Acute HCV: SLAM-C Study

	Group A - SOF + LDV N = 14	Group B - SOF + SIM N=15
Duration of therapy; weeks	4	8
Age; range (mean)	18-39 (27)	20-43 (31)
M:F	12:2	14:1
BMI, %	23:6	24:2
<b>Demographics</b>		
Caucasians	2	2
Hispanic	3	3
African American	9	10
Asian	0	0
<b>Genotype</b>		
1a	7	7
1b	7	8
Mean viral load, k	1,200	1,600
<b>IL28b</b>		
CC	4	3
CT	4	3
TT	6	9
T bilirubin	2	2.1
Creatinine	0.9	0.9
INR	1.2	1.0
ALT	87	102
Pre- Q80k	3 (all G1a)	2
Pre- 5A polymorphism	2	0
Post- Q80k	0 (no changes)	0 (no changes)
Post- 5A Rav's	1	0

Basu P, et al. 66th AASLD; San Francisco, CA; November 13-17, 2015; Abst. 1074.

## SLAM-C Study: Results

Undetectable	Group A SOF + LDV N=14	Group SOF + SIM N=15
Day 7, (n %)	13/14, 92.9%	13/15, 93.3%
4 Weeks, (n %)	14/14, 100% (ETVR)	14/15, 93.3% (1 dropped started IV drug use)
8 Weeks, (n %)	14/14, 100%	14/15, 93.3% (ETVR)
16 Weeks, (n %)	14/14, 100%, <b>SVR12</b>	14/15, 93.3%
20 Weeks, (n %) (per protocol)	(1 dropped, transferred to the prison)	13/13, 100%, <b>SVR12</b> (one was lost to follow-up-homeless)
Retention	13/14, 92.9%	13/15, 93.3%