ADVANCES IN CHRONIC HEPATITIS C:
MANAGEMENT AND TREATMENT

INDEPENDENT REPORTING ON AASLD 2016

COMPREHENSIVE EXPERT REVIEW AND DISCUSSION OF KEY PRESENTATIONS

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Safety and Efficacy of the Fixed-Dose Combination Regimen of MK-3682/Grazoprevir/MK-8408 With or Without Ribavirin in Non-cirrhotic or Cirrhotic Patients with Chronic HCV GT1, 2 or 3 Infection (Part B of C-CREST-1 & 2)

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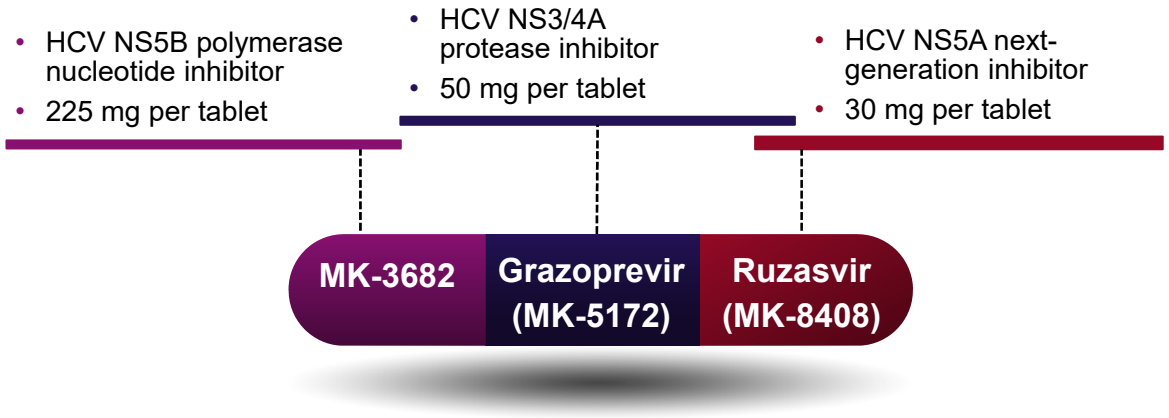
Abstract 110

C-CREST 1&2, Part B: MK-3682/Grazoprevir/Ruzasvir

- MK3 is a three-drug regimen formulated into a fixed-dose combination tablet. The regimen is given as two tablets, once-daily, without regard to food
- Triplet also called MK-3682B



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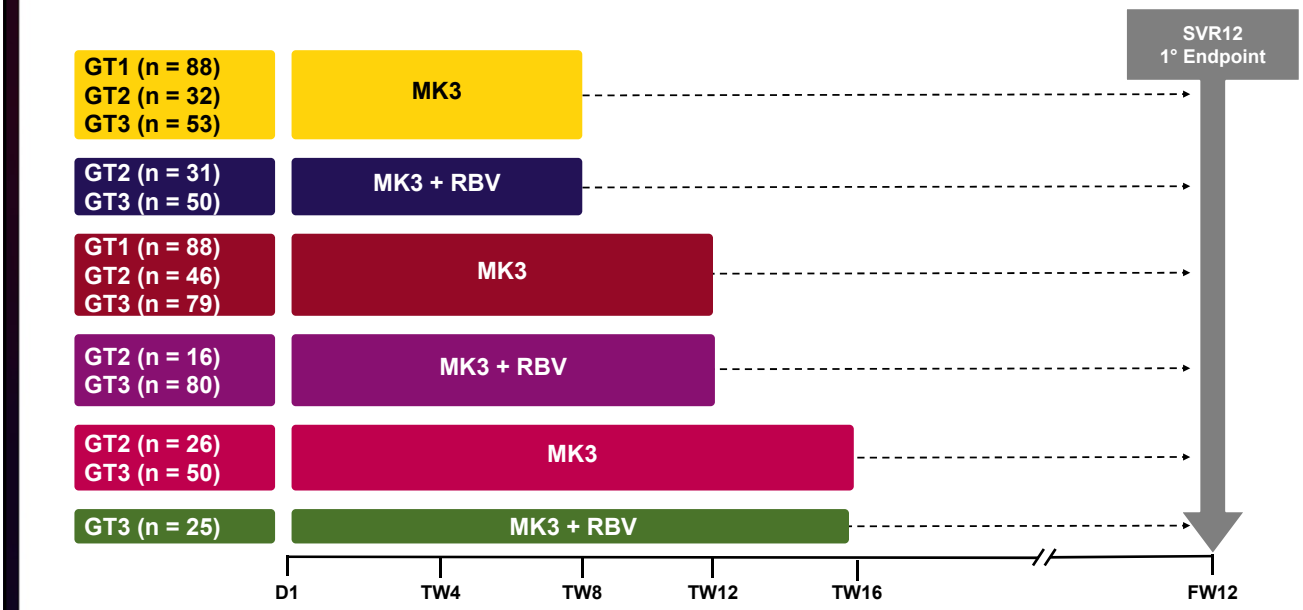
C-CREST 1&2, Part B:
(MK3: MK-3682/Grazoprevir/Ruzasvir; N=664)



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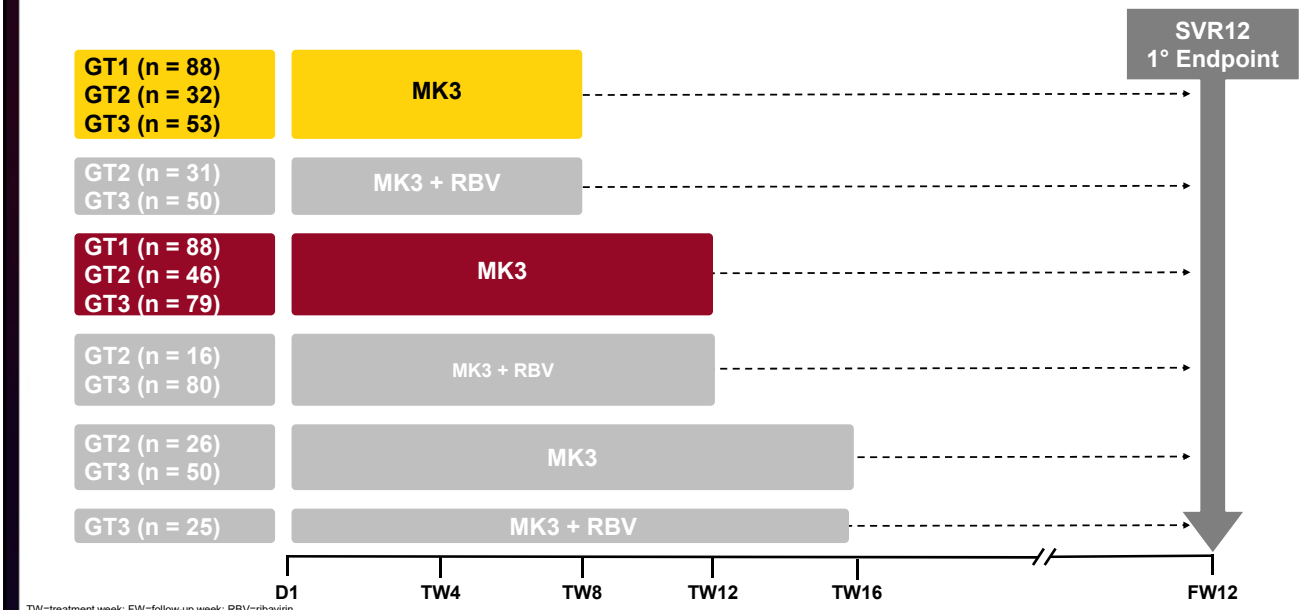

TW=treatment week; FW=follow-up week; RBV=ribavirin

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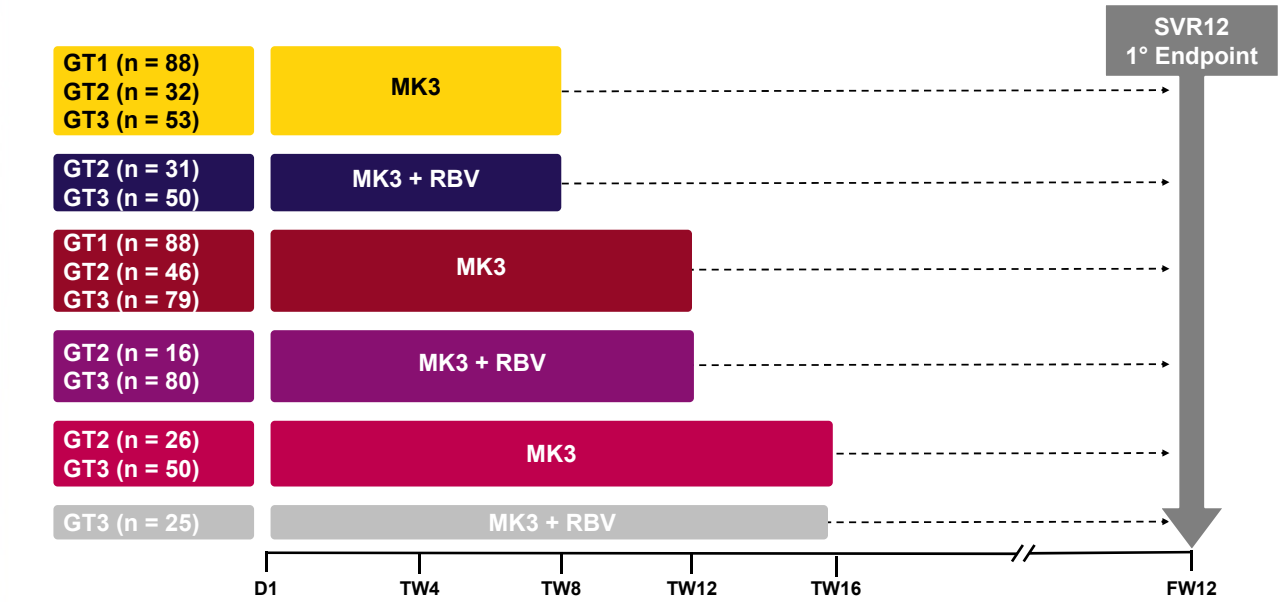

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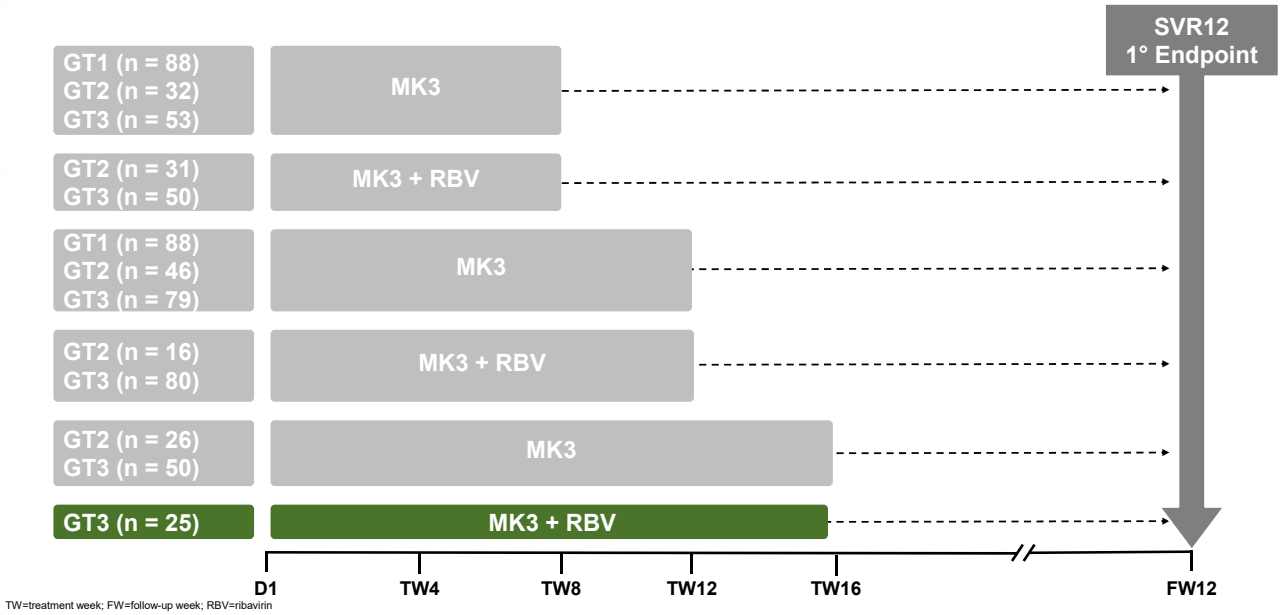

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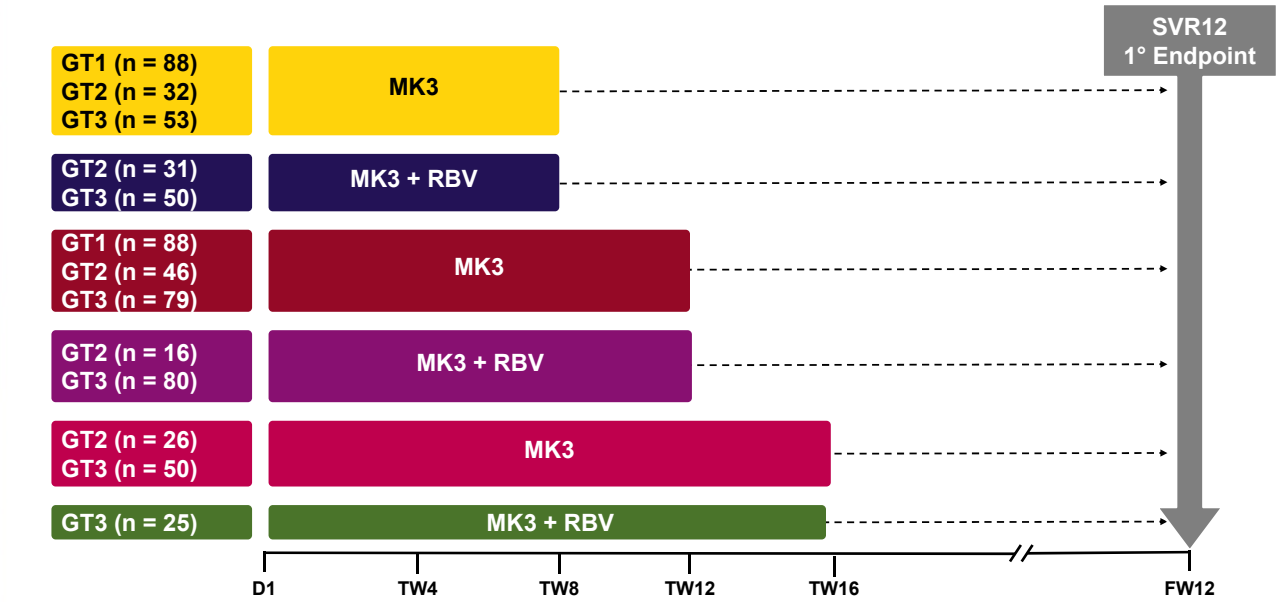

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C-CREST 1&2, Part B: Patient Demographics

	GT1, n=176	GT2, n=151	GT3, n=337	Overall GT1, GT2 and GT3, (N=664)
Male, n (%)	107 (61)	86 (57)	199 (59)	392 (59)
Race, White, n (%)	156 (89)	135 (89)	304 (90)	595 (90)
Race, Black (or African American), n (%)	18 (10)	8 (5)	4 (1)	30 (5)
Ethnicity: Hispanic or Latino, n (%)	33 (19)	37 (25)	13 (4)	83 (13)
Cirrhosis (Metavir F4), n (%)	75 (43)	57 (38)	117 (35)	249 (38)
HCV GT/subtype, n (%)				
GT1a	90 (51)	--	--	90 (14)
GT1b	86 (49)	--	--	86 (13)
Treatment-naïve, n (%)	176 (100)	151 (100)	189 (56)	516 (78)
Treatment (PR)-experienced, n (%)	--	--	148 (44)	148 (22)
HCV/HIV Co-infected, n (%)	9 (5)	4 (3)	10 (3)	23 (3)
Geographic Region, n (%)				
North America	87 (49)	87 (58)	125 (37)	299 (45)
European Union	78 (44)	56 (37)	128 (38)	262 (39)
Asian Pacific	4(2)	4 (3)	45 (13)	53 (8)
Middle East	7 (4)	4 (3)	39 (12)	50(8)

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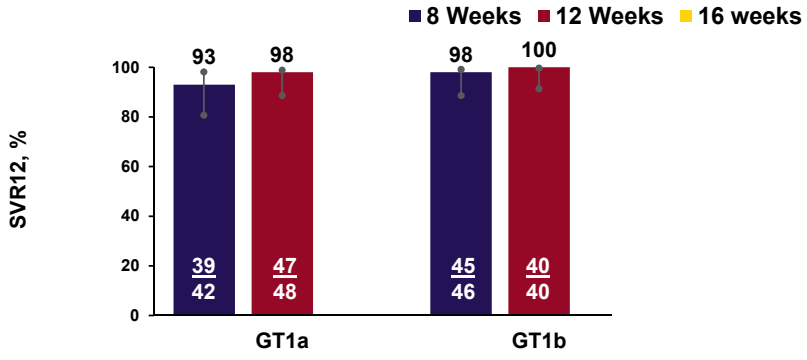
C-CREST 1&2, Part B: SVR12 (Full Analysis Set) 8, 12 or 16 Weeks



	GT1a		GT1b	
Relapse	2	0	1	0
Discontinuation (DR-AE)*	0	0	0	0
Reinfection*	1	0	0	0
Non-virologic failure*	0	1	0	0

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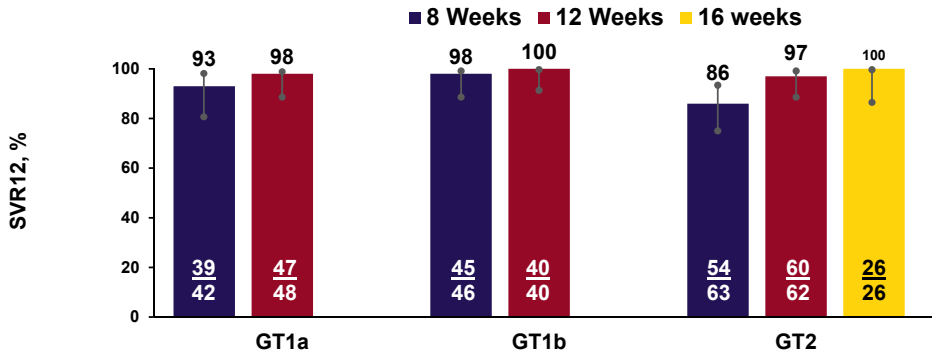
C-CREST 1&2, Part B: SVR12 (Full Analysis Set) 8, 12 or 16 Weeks



	GT1a		GT1b		GT2		
Relapse	2	0	1	0	7	0	0
Discontinuation (DR-AE)*	0	0	0	0	1	0	0
Reinfection*	1	0	0	0	0	0	0
Non-virologic failure*	0	1	0	0	1	2	0

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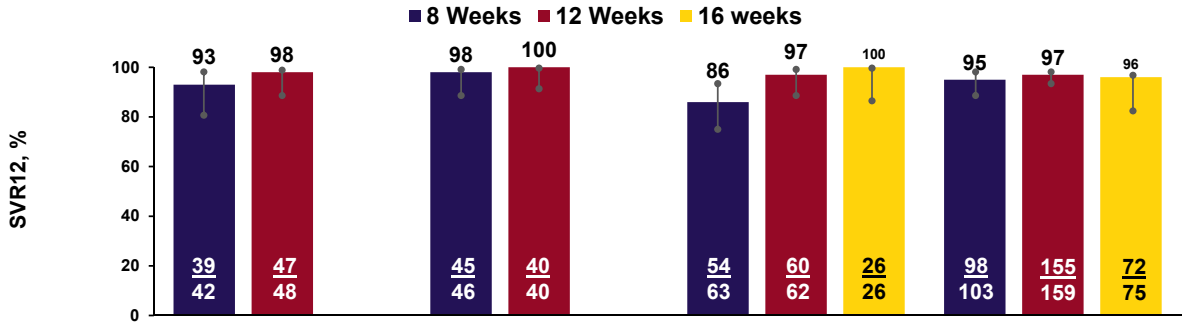
C-CREST 1&2, Part B: SVR12 by Genotype (Full Analysis Set)8, 12 or 16 Weeks



Relapse	2	0	1	0	7	0	0	4	3	2
Discontinuation (DR-AE)*	0	0	0	0	1	0	0	0	0	0
Reinfection*	1	0	0	0	0	0	0	0	0	0
Non-virologic failure*	0	1	0	0	1	2	0	1	1	1

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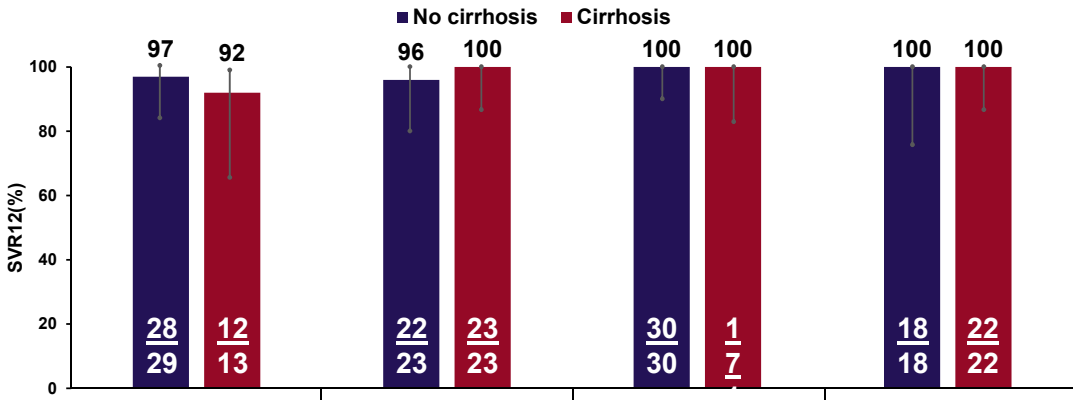
C-CREST 1&2, Part B: SVR12 (Per Protocol) GT1 Patients With or Without Cirrhosis



Subgenotype	1a		1b		1a		1b	
Duration	8 Weeks		8 Weeks		12 Weeks		12 Weeks	
Relapses	1	1	1	0	0	0	0	0

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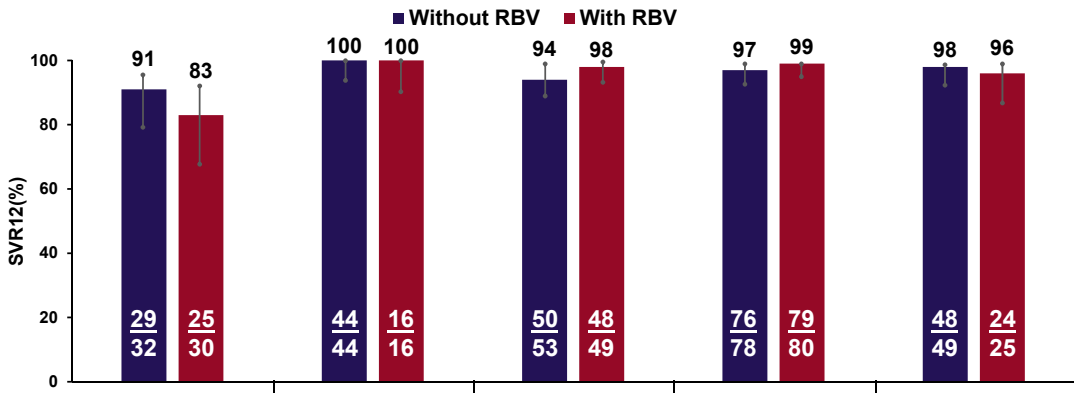
C-CREST 1&2, Part B: SVR12 (Per Protocol) GT2 or GT3 Patients With or Without Ribavirin



Genotype	GT2		GT2		GT3		GT3		GT3	
Duration	8 Weeks		12 Weeks		8 Weeks		12 Weeks		16 Weeks	
Relapse	3	4	0	0	3	1	2	1	1	1
Discontinuation (DR-AE)	0	1	0	0	0	0	0	0	0	0

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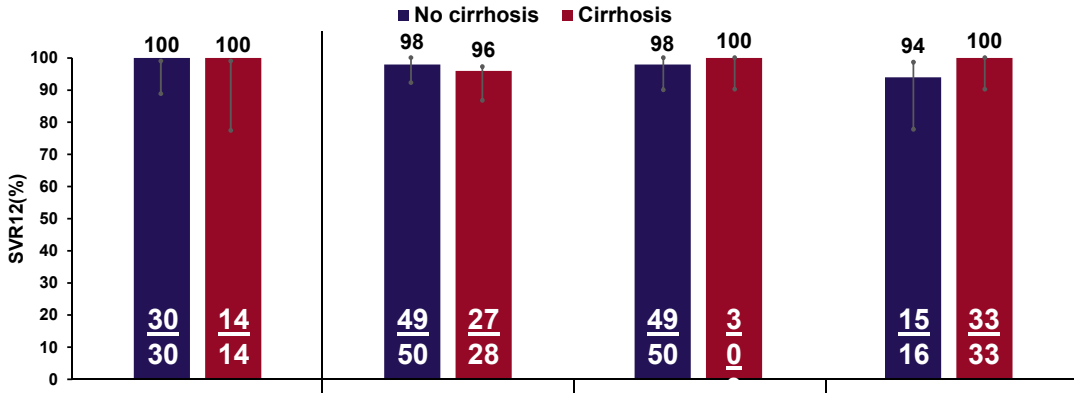
C-CREST 1&2, Part B: SVR12 (Per Protocol)GT2 or GT3 Patients With or Without Cirrhosis



Subgenotype	GT2		GT3		GT3		GT3	
Duration	12 Weeks No RBV		12 Weeks, No RBV		12 Weeks, + RBV		16 Weeks, No RBV	
Relapses	0	0	1	1	1	0	1	0

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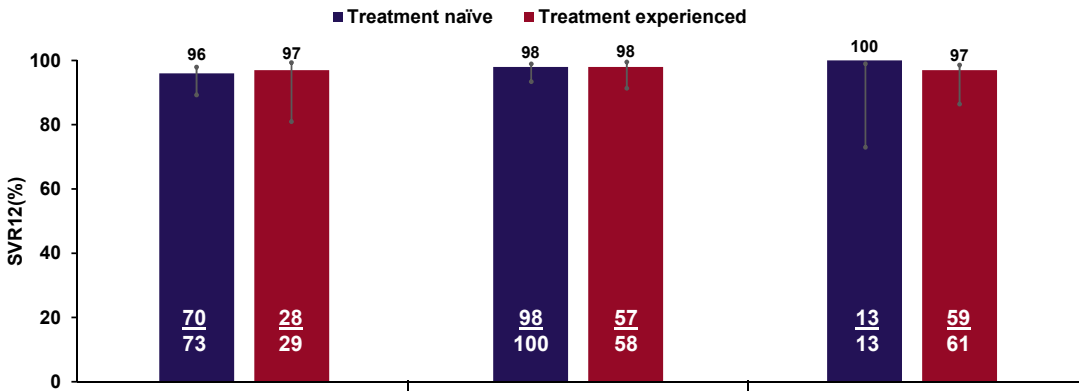
C-CREST 1&2, Part B: SVR12 (Per Protocol) GT3 Patients by Prior Treatment Experience



	8 Weeks		12 Weeks		16 Weeks	
Relapse	3	1	2	1	0	2

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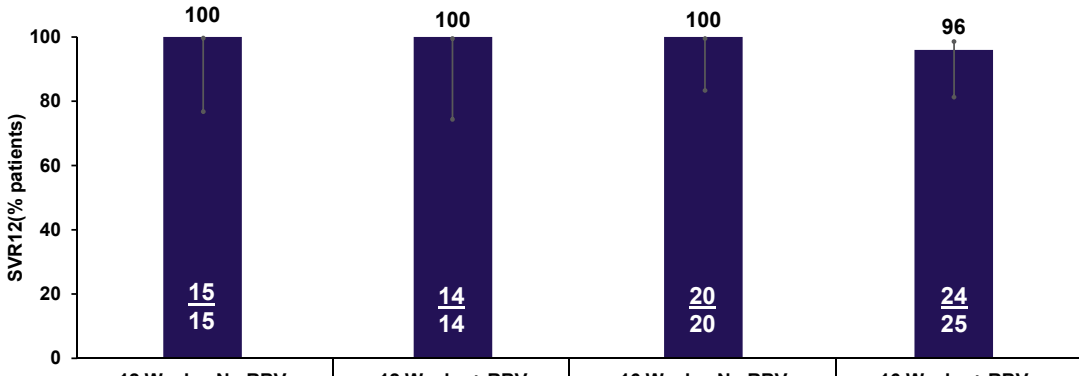
C-CREST 1&2, Part B: SVR12 (Per Protocol) GT3 Treatment-Experienced Patients with Cirrhosis



	12 Weeks, No RBV	12 Weeks + RBV	16 Weeks, No RBV	16 Weeks + RBV
Relapse	0	0	0	1

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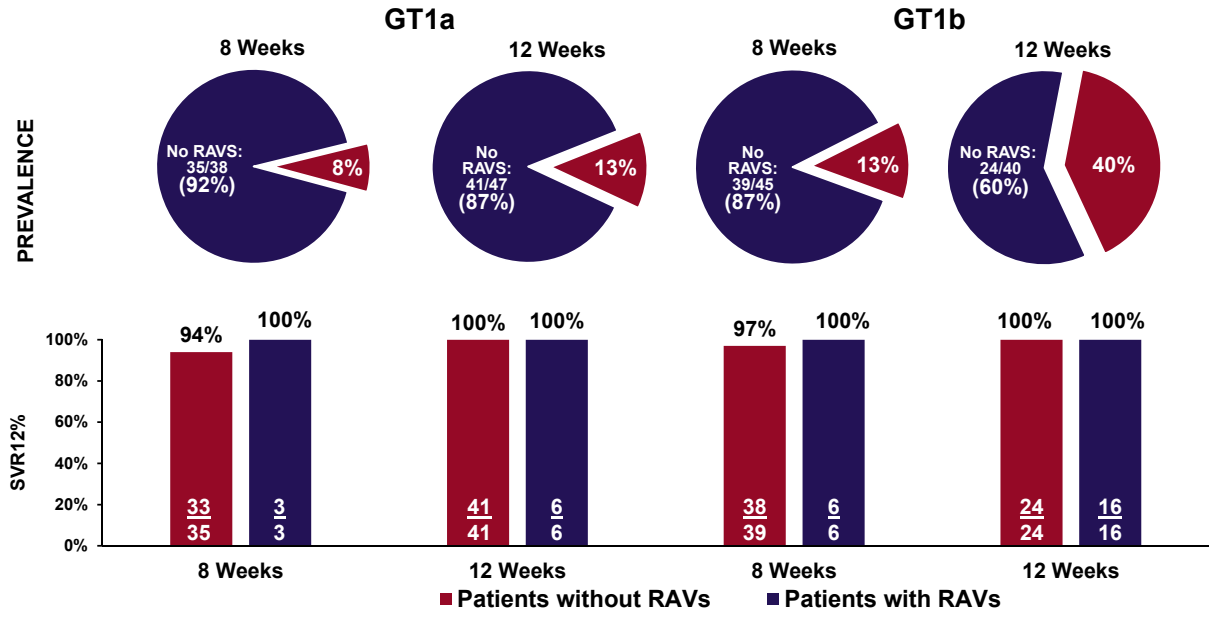
C-CREST 1&2, Part B: Selected NS5A RAVs (28, 30, 31, 93) Prevalence and Impact on Efficacy in GT1



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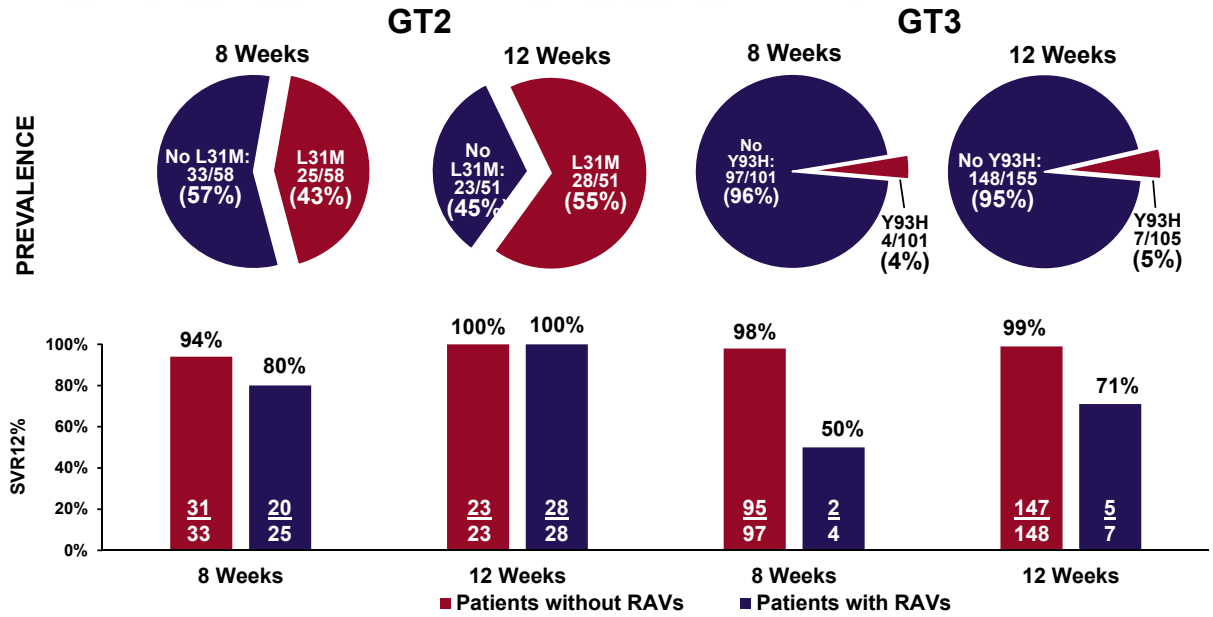
C-CREST 1&2, Part B: Selected NS5A RAVs Prevalence and Impact on Efficacy of L31M in GT2 and Y93H in GT3



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Conclusions

- MK3 (MK-3682/grazoprevir/ruzasvir) for 8 or 12 weeks was highly effective in GT1 patients (SVR12 = 97%)
- MK3 for 12 or 16 weeks was highly effective in GT2 patients (SVR12 = 98%)
  - The addition of ribavirin did not increase SVR12
- MK3 for 8, 12 or 16 weeks was highly effective in GT3 treatment-naïve or treatment-experienced patients (SVR12 = 96%)
  - The addition of ribavirin did not increase SVR12
  - Efficacy was maintained in GT3 treatment-experienced patients with cirrhosis (SVR12 = 99%)
- Treatment with MK3 was generally safe and well-tolerated

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