

A 12-Week Interferon-free Treatment Regimen with ABT-450/r, ABT-267, ABT-333 and Ribavirin Achieves SVR12 Rates (Observed Data) of 99% in Treatment-Naïve Patients and 93% in Prior Null Responders with HCV Genotype 1 Infection

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Abstract LB-1

M11-652 Study Design

	N	Regimen/Duration	ABT-450/r Dose (QD)
Treatment-naïve	80	ABT-450 ABT-267 ABT-333	150/100
	41	ABT-450 ABT-333 RBV RBV	150/100
	79	ABT-450 ABT-267 RBV	100/100,200/100
	79	ABT-450 ABT-267 ABT-333	150/100
	79	ABT-450 ABT-267 ABT-333 RBV	100/100,150/100
	80	ABT-450 ABT-267 ABT-333 RBV	100/100,150/100
Null Responder	45	ABT-450 ABT-267 RBV	200/100
	45	ABT-450 ABT-267 ABT-333 RBV	100/100,150/100
	43	ABT-450 ABT-267 ABT-333 RBV	100/100,150/100

ABT-267 25mg QD; ABT-333 400mg BID; RBV weight-based 1000-1200 mg daily dose divided BID. All patients to be followed through 48 weeks post-treatment

Response Rates

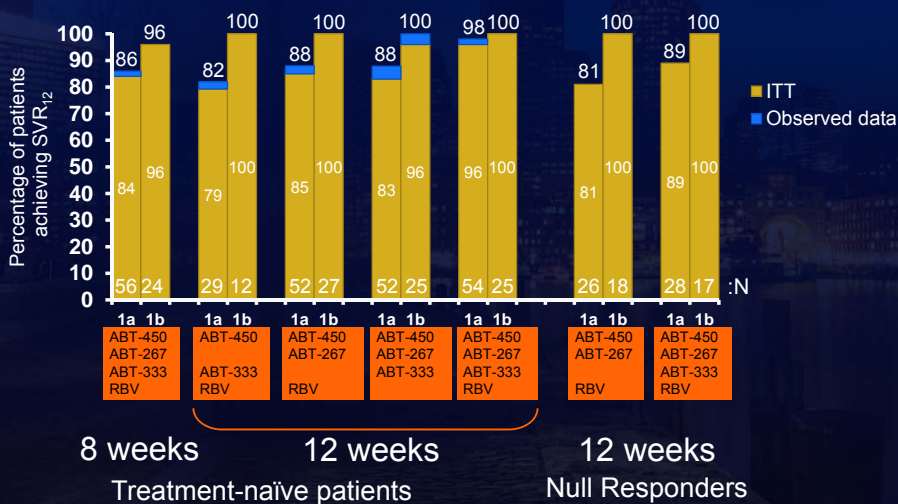
Duration	Treatment-naïve Patients					Null Responders	
	8 wks	12 wks			12 wks		
Regimen	450/r	450/r	450/r	450/r	450/r	450/r	450/r
	267	267	267	267	267	267	267
	333	333	333	333	333	333	333
	RBV	RBV	RBV	RBV	RBV	RBV	RBV
Number dosed	80	41	79	79	79	45	45
Breakthroughs (N)	0	1	1	1	0	0	3
Relapses (N)	9	4	5	5	1	5	0
Lost to follow-up or withdrawn consent prior to SVR ₁₂	1	1	2	4	1	0	0
SVR ₁₂ rate (ITT) ^a , % (n/N)	87.5% (70/80)	85.4% (35/41)	89.9% (71/79)	87.3% (69/79)	97.5% (77/79)	88.9% (40/45)	93.3% (42/45)
SVR ₁₂ rate (Observed data) ^b , % (n/N)	88.6% (70/79)	87.5% (35/40)	92.2% (71/77)	92.0% (69/75)	98.7% (77/78)	88.9% (40/45)	93.3% (42/45)

^aITT: Intent-to-treat population, includes all patients who received at least one dose of study drug

^bObserved data: Excludes patients with values missing for reasons other than virologic failure or discontinuation due to AEs

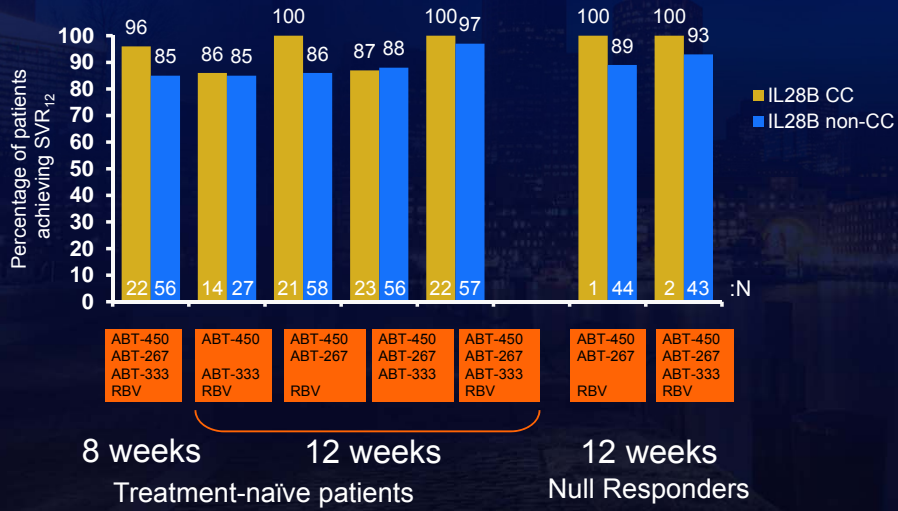
Kowdley K, et al. 63rd AASLD; Boston, MA; November 9-13, 2012; Abst. LB-1.

SVR₁₂ Rates in M11-652 by HCV Subtype (N=448)



Kowdley K, et al. 63rd AASLD; Boston, MA; November 9-13, 2012; Abst. LB-1.

ITT SVR₁₂ Rates by IL28B Genotype



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