

# 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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### All-Oral Treatment with Daclatasvir (DCV) Plus Sofosbuvir (SOF) Plus Ribavirin (RBV) for 12 or 16 Weeks in HCV Genotype (GT) 3-Infected Patients with Advanced Fibrosis or Cirrhosis: The ALLY-3+ Phase 3 Study

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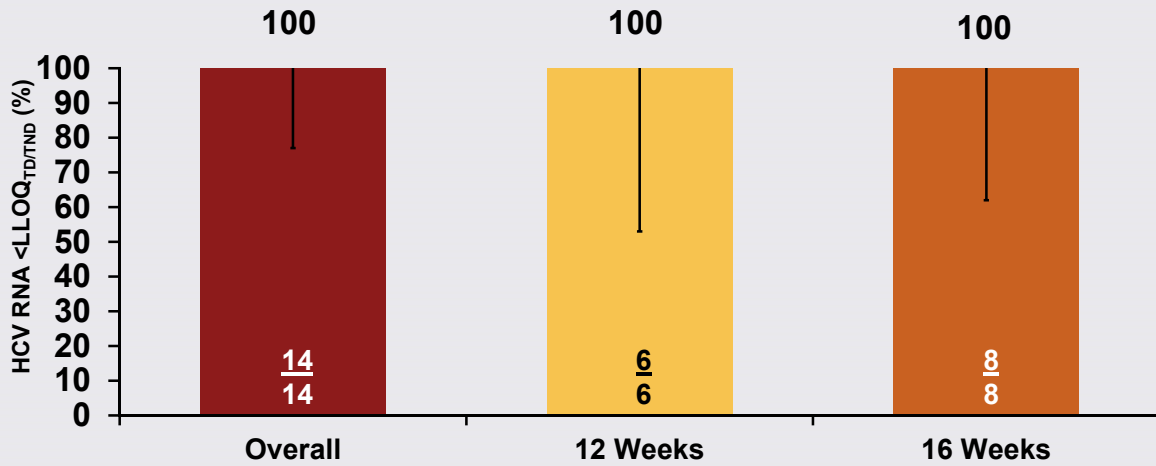
Abstract LB-3

## ALLY-3: Baseline Demographics and Disease Characteristics

	DCV+SOF+RBV Total N = 50	DCV+SOF+RBV 12 Weeks N = 24	DCV+SOF+RBV 16 Weeks N = 26
Age, median (range) yrs	53.5 (36–73)	53.0 (36–73)	56.0 (42–62)
Male, n (%)	40 (80)	18 (75)	22 (85)
Race, n (%)			
White	49 (98)	23 (96)	26 (100)
Asian	1 (2)	1 (4)	0
IL28B non-CC, n (%)	28 (56)	13 (54)	15 (58)
HCV RNA, median (range) log <sub>10</sub> IU/mL	6.87 (4.6–7.8)	6.70 (4.6–7.6)	6.91 (4.7–7.8)
HCV RNA category (IU/mL), n (%)			
≥2 million	38 (76)	18 (75)	20 (77)
≥6 million	26 (52)	11 (46)	15 (58)
Fibrosis stage, <sup>a</sup> n (%)			
Advanced fibrosis (F3)	14 (28)	6 (25)	8 (31)
Cirrhosis (F4)	36 (72)	18 (75)	18 (69)
Albumin, median (range) g/L	43 (33–48)	43.0 (33–47)	42.5 (34–48)
Platelets, median (range) × 10 <sup>9</sup> cells/L	161 (63–324)	161 (63–299)	155 (84–324)
Prior HCV treatment experience, n (%)			
Naive	13 (26)	6 (25)	7 (27)
Experienced <sup>b</sup>	37 (74)	18 (75)	19 (73)
IFN-based regimens	31 (62)	15 (63)	16 (62)
SOF-based regimens <sup>c</sup>	6 (12)	3 (13)	3 (12)

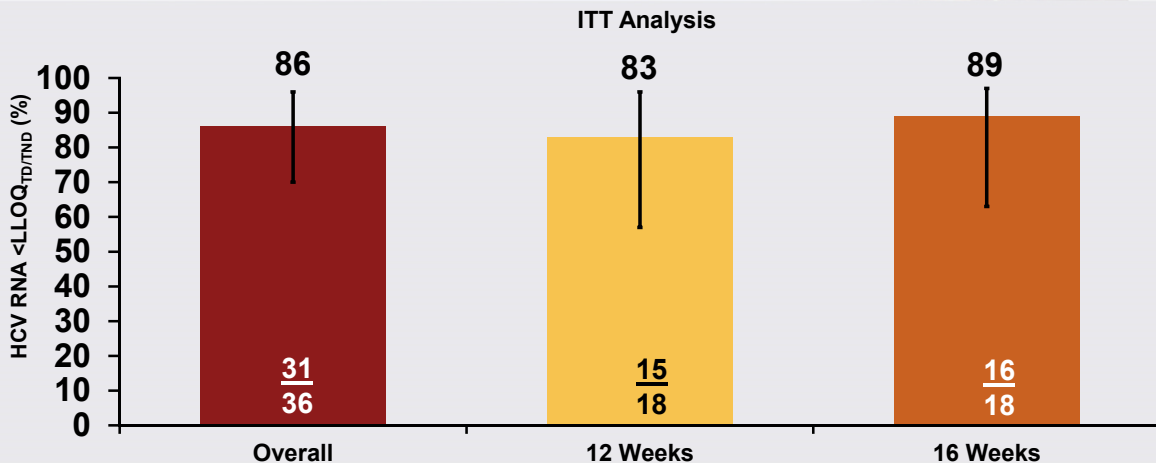
Leroy V, et al. 66th AASLD, San Francisco, CA; November 13–17, 2015; Abst. LB-3.

## ALLY-3+ STUDY: Results in F3-F4 Fibrosis



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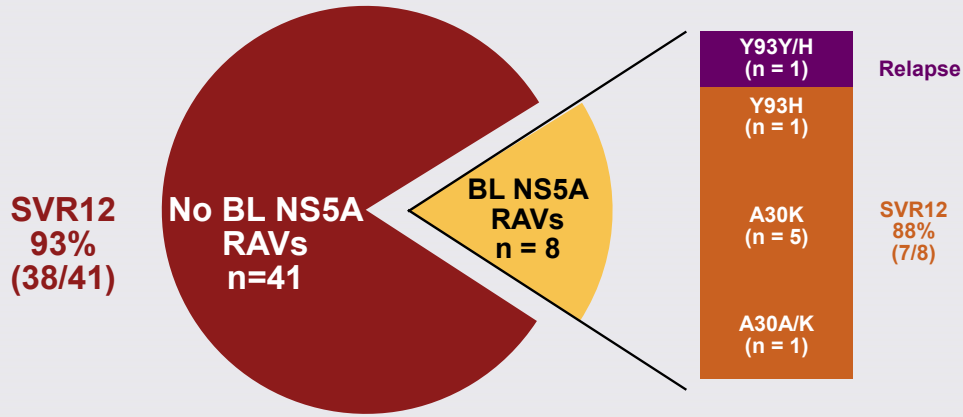
## ALLY-3+ STUDY: Results in Cirrhosis



	Overall	12 Weeks	16 Weeks
<b>VBT<sup>a</sup></b>	0	0	0
<b>Relapse<sup>b</sup></b>	4	2	2
<b>Death<sup>c</sup></b>	1	1	0

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## ALLY-3+ STUDY: Effect of NS5A RAVS



- At failure, all 4 patients who relapsed had NS5A-Y93H
- No SOF-associated RAVs in NS5B were observed at baseline or relapse (sensitivity  $\geq 1\%$ )

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## ALLY-3+ STUDY: Summary

- Overall 90% SVR12 in ALLY 3+; 92% excluding those who died
- 88% in 12 week arm and 92% in 16 week arm
- 100% SVR12 in advanced fibrosis
- 88% SVR12 in cirrhosis; 89% excluding death
- No difference for cirrhosis 12 vs 16 weeks (83% vs 89%)
- Safety; good profile, no grade 4 labs
- Nothing notable in common AE profile

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