Treatment-Naïve and Treatment-Experienced

Daclatasvir + Sofosbuvir + RBV in GT3 with Advanced Liver Disease

ALLY-3+ Study

Leroy V, et al. Hepatology 2016 Jan 28. [Epub ahead of print]

Daclatasvir + Sofosbuvir + RBV for HCV GT 3 Advanced Liver Disease

ALLY-3+ Trial: Study Features

ALLY 3+ Trial: Features

- **Design**: Phase 3 open-label randomized trial of daclatasvir (DCV) and sofosbuvir (SOF) plus ribavirin (weight-based dosing) for 12 versus 16 weeks in treatment-naïve or experienced, chronic HCV GT 3 with advanced fibrosis or compensated cirrhosis
- **Setting**: 10 clinical centers in France and Australia
- **Entry Criteria**
  - Chronic HCV genotype 3
  - Treatment-naïve or treatment-experienced (prior NS5A experience excluded)
  - HCV RNA ≥10,000 IU/ml
  - Required confirmation of advanced fibrosis or compensated cirrhosis
  - Fibrosis & cirrhosis determined by liver biopsy, FibroScan, FibroTest, APRI
- **End-Points**: Primary = SVR12

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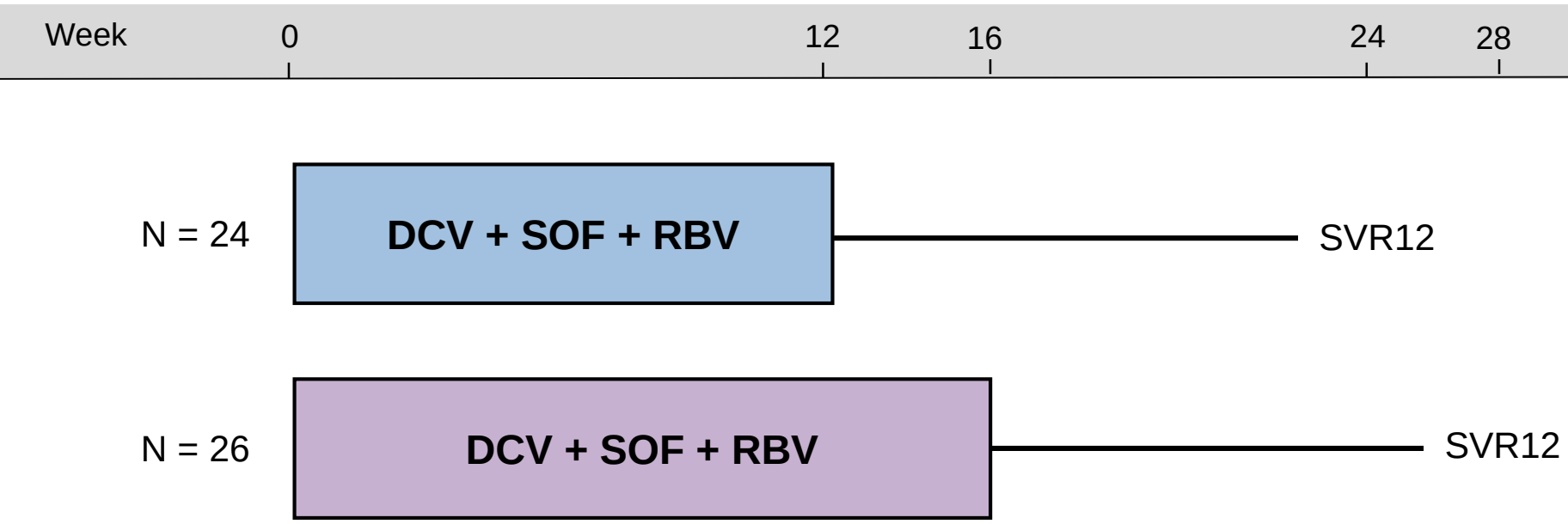
ALLY-3+ Trial: Design



Drug Dosing

Daclatasvir (DCV): 60 mg once daily

Sofosbuvir (SOF: 400 mg once daily

Ribavirin (RBV): GT1, given weight-based and divided bid (1000 mg/day if < 75kg or 1200 mg/day if ≥ 75kg)

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ALLY-3+ Trial: Patient Characteristics

Characteristic	12 weeks (n=24)	16 weeks (n=26)
Male	18 (75%)	22 (85%)
Median age, years (range)	53 (36-73)	56 (42-62)
Race White Asian	 23 (96%) 1 (4%)	26 (100%)
HCV RNA ≥800,000 IU/ml	20 (83%)	21 (81%)
Stage F3 (METAVIR) Compensated cirrhosis (F4)	6 (25%) 18 (75%)	8 (31%) 18 (69%)
Prior treatment status Naïve IFN-experienced SOF-experienced	 6 (25%) 15 (63%) 3 (12%)	 7 (27%) 16 (62%) 3 (11%)
DCV NS5A RAVs	7 (27%)	1 (4%)

IFN=peginterferon, SOF=sofosbuvir, DCV=daclatasvir, RAVs=resistance-associated variants

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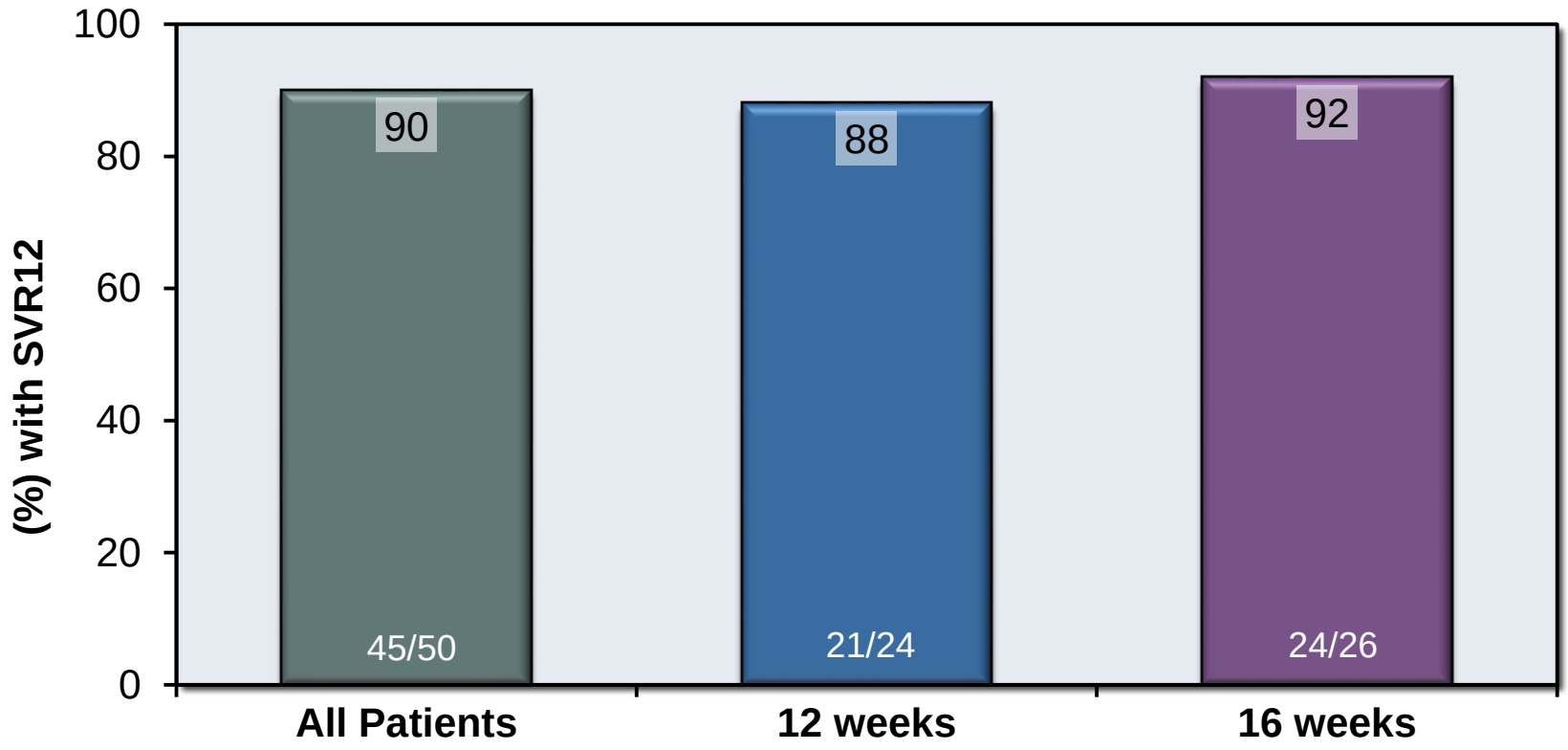
ALLY-3+ Trial: Results

ALLY-3+: SVR12 by Treatment Arm



SVR12 rates determined by intent-to-treat analysis

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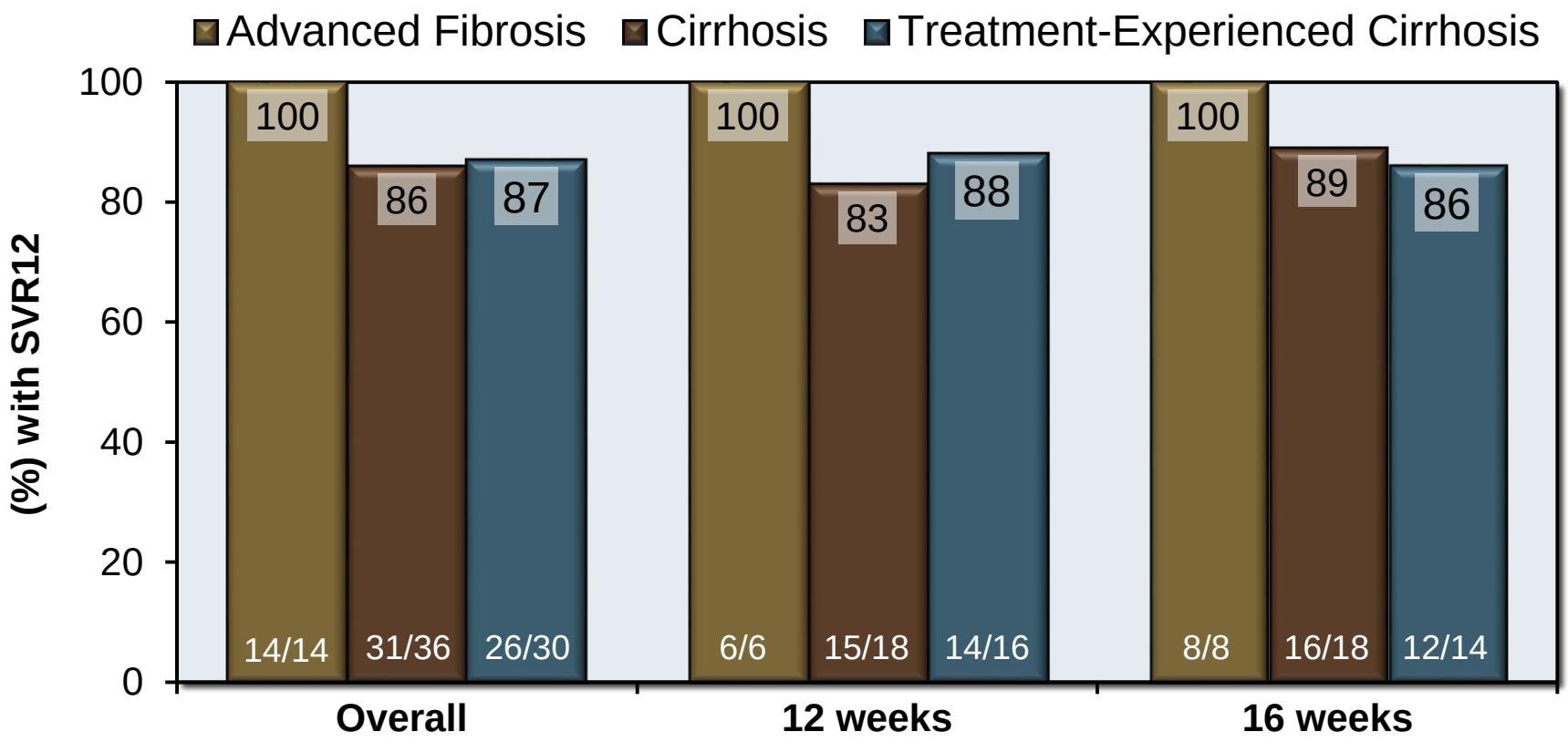
ALLY-3+ Trial: Results

ALLY-3+: SVR12 by Cirrhosis Status



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ALLY-3+ Trial: Safety

Adverse Event (AE)	12 weeks (n=24)	16 weeks (n=26)
Serious AEs	2 (8%)	3 (11.5%)
AE leading to discontinuation	0	0
Ribavirin dose reduction	2 (8%)	2 (8%)
AEs in ≥10% of patients		
Insomnia	8 (33%)	7 (27%)
Fatigue	6 (25%)	7 (27%)
Headache	7 (29%)	5 (19%)
Irritability	5 (21%)	2 (8%)
Asthenia	2 (8%)	5 (19%0
Diarrhea	1 (4%)	4 (15%)
Dyspnea	2 (8%)	3 (11%)
Grade 3-4 Lab AEs		
Hemoglobin	0	1 (4%)
Total bilirubin	1 (4%)	1 (4%)

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ALLY-3+ Trial: Conclusion

Conclusion: “The all-oral regimen of daclatasvir-sofosbuvir-ribavirin was well tolerated and resulted in high and similar SVR12 after 12 or 16 weeks of treatment among genotype 3-infected patients with advanced liver disease, irrespective of prior HCV treatment experience.”

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This slide deck is from the University of Washington's *Hepatitis C Online* and *Hepatitis Web Study* projects.

Hepatitis C Online

www.hepatitisc.uw.edu

Hepatitis Web Study

http://depts.washington.edu/hepstudy/

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Hepatitis web study