Treatment Naïve and Treatment Experienced

Ledipasvir-Sofosbuvir + Ribavirin in HCV GT 1,4

SOLAR-1 (Post Transplant)

Reddy KR, al. 65th AASLD. 2014: Abstract 8.

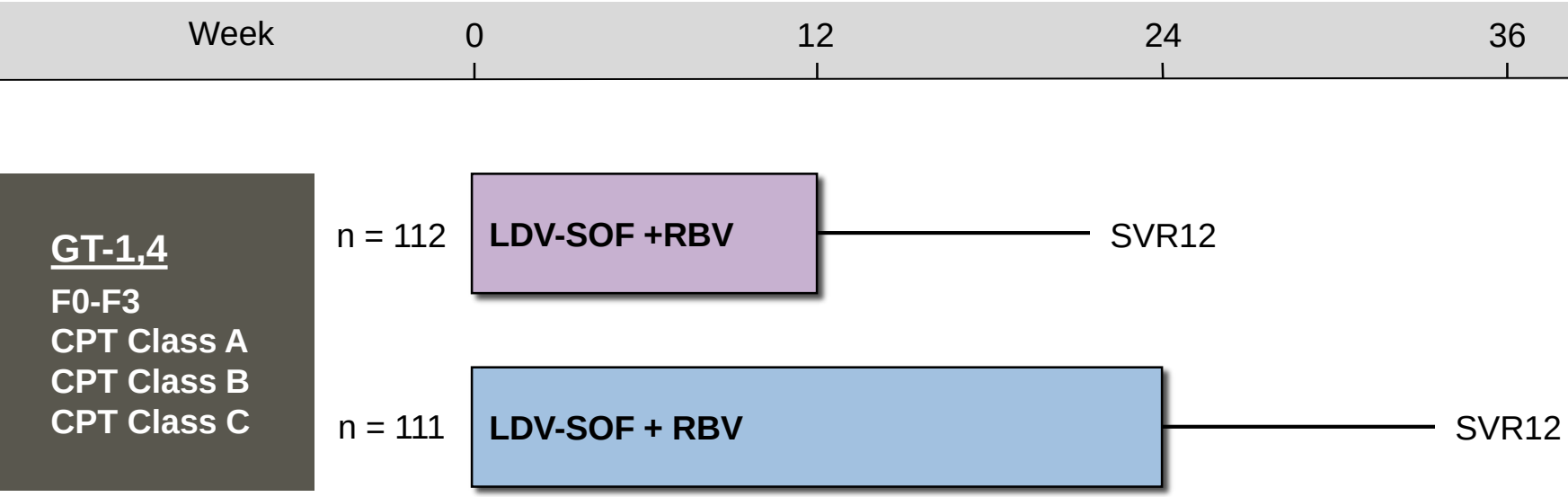
Ledipasvir-Sofosbuvir + Ribavirin in HCV GT 1,4
SOLAR-1 (Post Transplant): Features

SOLAR-1 (Post Transplant): Design

- **Design**: Phase 2, randomized, prospective, multicenter trial, using fixed-dose combination of ledipasvir-sofosbuvir plus ribavirin for 12 or 24 weeks in treatment-naïve and treatment-experienced patients with GT1 or 4 HCV infection post-liver transplantation
- **Setting**: multicenter in United States
- **Entry Criteria**
  - Adults with Chronic HCV Genotype 1 or 4 (n=223)
  - Treatment-naïve or treatment experienced post liver transplant
  - Stratified at screening: F0-F3, Child-Pugh-Turcotte Class A, B, C
  - ≥ 3 months from liver transplant
  - Total bilirubin ≤ 10 mg/dL; Creatinine clearance ≥ 40 mL/min
  - Hemoglobin ≥ 10 g/dL; Platelet count > 30,000/mm^3
  - No hepatocellular carcinoma
- **Primary End-Point**: SVR12

Source: Reddy KR, al. 65th AASLD. 2014: Abstract 8.

Ledipasvir-Sofosbuvir + Ribavirin in HCV GT 1,4
SOLAR-1 (Post Transplant): Study Design



Abbreviations: LDV= ledipasvir; SOF = sofosbuvir; RBV = ribavirin

Drug Dosing

Ledipasvir-sofosbuvir (90/400 mg): fixed dose combination; one pill once daily

Ribavirin Dosing

- FO-F3: weight-based and divided bid (1000 mg/day if < 75 kg or 1200 mg/day if ≥ 75 kg)
- Child-Pugh-Turcotte Class B, C: started at 600 mg/day and escalated up to maximum of 1200 mg/day

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Ledipasvir-Sofosbuvir + Ribavirin in HCV GT 1,4
SOLAR-1 (Post Transplant): Baseline Characteristics

Baseline Characteristic	F0-F3 n=111	CTP A n=51	CPT B n=52	CPT C n=9
Median age, years (range)	59 (26-72)	60 (21-81)	61 (37-72)	60 (57-66)
Male sex, n (%)	91 (82)	41(80)	45 (87)	9 (100)
White, n (%)	99 (89)	41 (80)	45 (87)	8 (89)
Median years from OLT	2.9	8.1	5.6	5.2
HCV RNA, $\log_{10}$ IU/ml (median)	6.6	6.6	6.4	6.3
IL28B non CC, n (%)	90 (81)	43 (84)	44 (85)	6 (67)
HCV Genotype, n (%)				
1a	80 (72)	34 (67)	38 (73)	7 (78)
1b	30 (27)	17 (33)	13 (25)	2 (22)
4	1 (1)	0	1 (2)	0
Prior Treatment	87 (78)	46 (90)	44 (85)	8 (89)

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Ledipasvir-Sofosbuvir + Ribavirin in HCV GT 1,4
SOLAR-1 (Post Transplant): Baseline Liver Status

Baseline Characteristic	F0-F3 n=111	CTP A n=51	CPT B n=52	CPT C n=9
Meld Score, n (%) <10 10-15 16-20 21-25	 NA NA NA NA	 28 (55) 20 (39) 3 (6) 0	 13 (25) 33 (63) 4 (8) 2 (4)	 1 (11) 5 (56) 2 (22) 1 (11)
Median bilirubin, mg/dL (range)	0.7 (0.3-3.6)	0.8 (0.2-2.9)	1.2 (0.5-3.7)	2.1 (0.7-9.9)
Median albumin, g/L (range)	3.8 (2.4-4.6)	3.7 (2.6-4.5)	3.2 (2.3-4.2)	2.4 (1.6-2.9)
Median INR, (range)	1.0 (0.9-1.3)	1.1 (0.9-2.4)	1.2 (0.9-3.4)	1.3 (1.0-1.5)
Median platelets, x 10^3 µL (range)	146 (71-249)	108 (41-358)	93 (32-225)	79 (54-189)
Ascites, n (%)	2 (2)	2 (4)	40 (77)	9 (100)
Creatinine Clearance (mL/min)	65	62	59	67
Encephalopathy, n (%)	1 (1)	3 (6)	23 (44)	7 (78)

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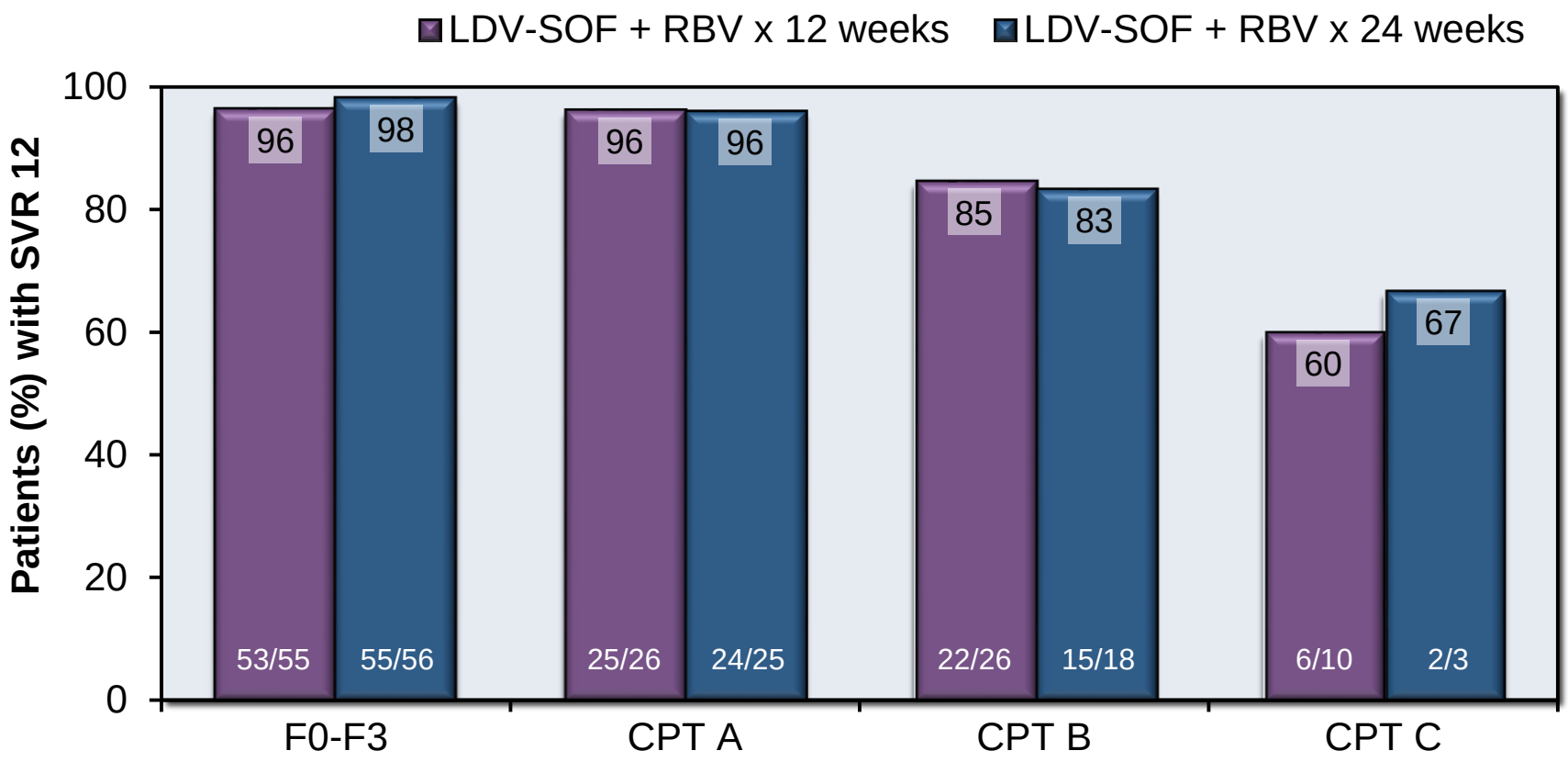
SOLAR-1 (Post Transplant): Preliminary Study Results



8 subjects CPT B 24 weeks and 1 CPT C 24 week had not reached SVR12 timepoint

Source: Reddy KR, al. 65th AASLD. 2014: Abstract 8.

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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