ADVANCES IN CHRONIC HEPATITIS C:
MANAGEMENT AND TREATMENT
REPORTING ON EASL 2016
COMPREHENSIVE EXPERT REVIEW AND DISCUSSION OF KEY PRESENTATIONS
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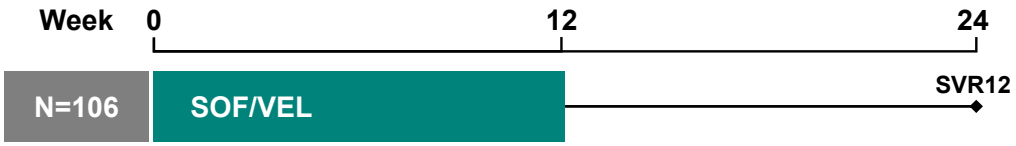
SOFOSBUVIR/VELPATASVIR FIXED DOSE COMBINATION FOR 12 WEEKS IN PATIENTS CO-INFECTED WITH HCV AND HIV-1: THE PHASE 3 ASTRAL-5 STUDY

D. Wyles, N. Brau, S. Kottilil, E. Daar, K. Workowski, A. Luetkemeyer, O. Adeyemi, P. Ruane, B. Doehle, K.C. Huang, A. Osinusi, J. McNally, D. Brainard, J. McHutchison, S. Naggie, M. Sulkowski

Abstract PS104

Study Design



- Open-label, single-arm, multicenter, Phase 3 study
- Broad inclusion criteria
  - HCV genotypes 1–6
  - Treatment naïve or experienced
  - 30% with compensated cirrhosis
  - On stable ART for ≥8 weeks, CD4 cell count ≥100 cells/mm^3, and HIV RNA ≤50 copies/mL
- Inclusion of non-nucleoside reverse-transcriptase inhibitor (NNRTI), integrase inhibitor, and protease inhibitor (PI) regimens with TDF/FTC or ABC/3TC

3TC, lamivudine; ABC, abacavir; FTC, emtricitabine; TDF, tenofovir disoproxil fumarate.

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HIV Baseline Characteristics

	SOF/VEL n=106
Mean CD4 count, cells/μL (range)	**598 (183–1513)**
NRTI Backbone	
TDF-based with boosted agent (RTV or COBI)	56 (53)
TDF-based without boosted agent	35 (33)
ABC/3TC-base	15 (14)
ART Use at Baseline	
PI (DRV, LPV or ATV)	50 (47)
NNRTI (RPV)	13 (12)
Integrase inhibitor (RAL or EVG)	36 (34)
Other (>1 of the above classes)	7 (7)

NRTI, nucleoside-analog reverse-transcriptase inhibitor; 3TC, lamivudine; ABC, abacavir; ATV, atazanavir; COBI, cobicistat; DRV, darunavir; EVG, elvitegravir; LPV, lopinavir; RAL, raltegravir; RPV, rilpivirine; RTV, ritonavir.

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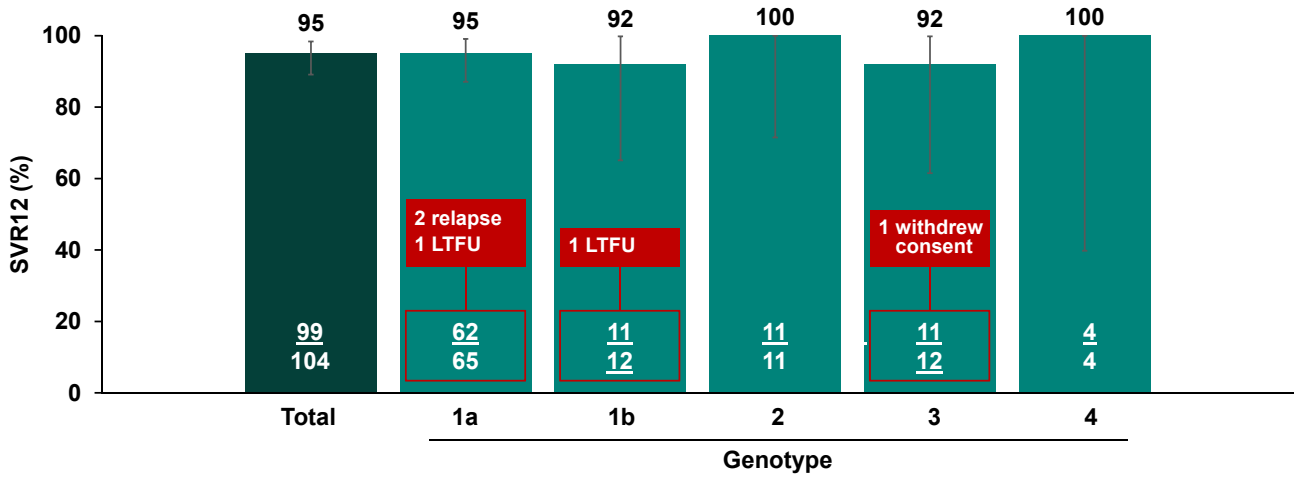
SVR12 by Genotype



LTFU, lost to follow-up. Error bars represent 95% confidence intervals

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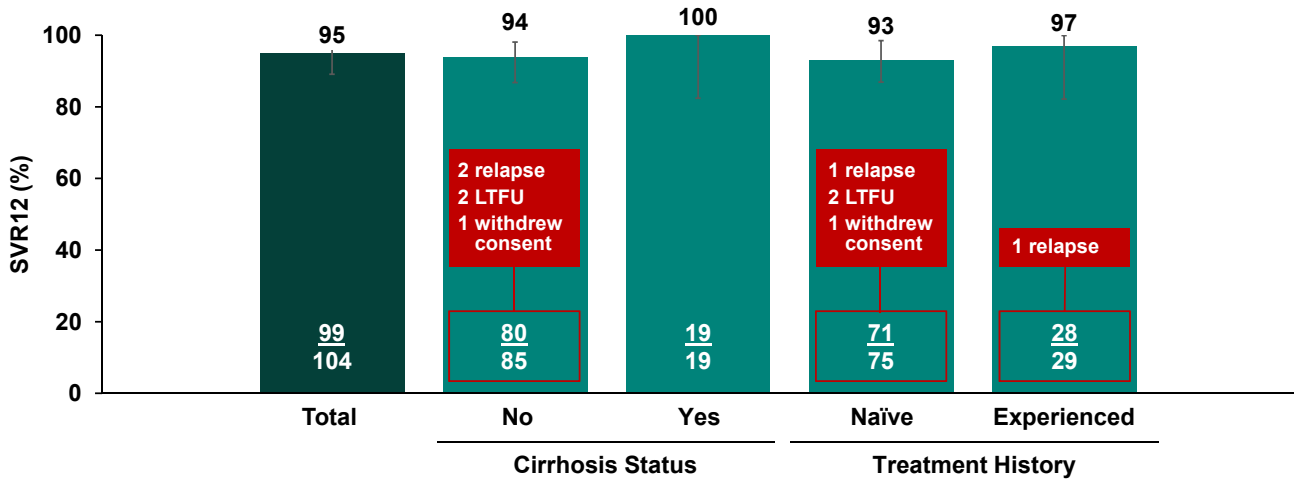
SVR12 by Cirrhosis or Prior Treatment



Error bars represent 95% confidence intervals.

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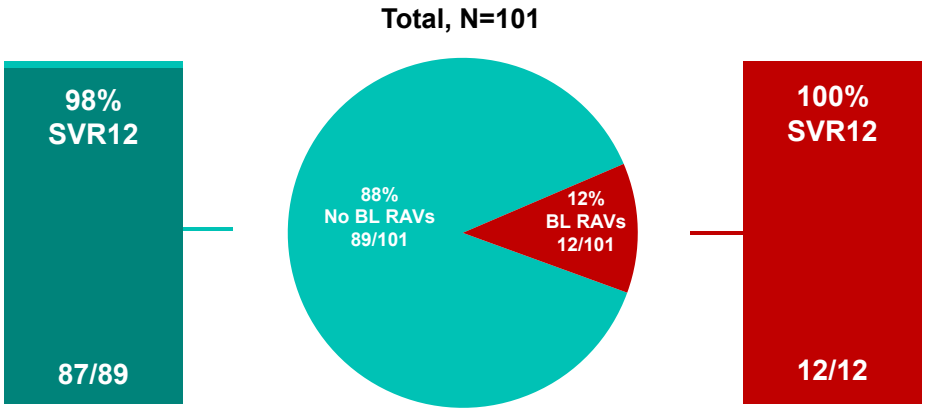
SVR12 by Baseline NS5A RAVs



All Patients with NS5A Class RAVs Achieved SVR

- 15% cutoff: 12/12 patients
- 1% cutoff: 19/19 patients

NS5A class RAVs; 15% deep-sequencing cut-off.
5 patients were excluded from analysis (2 pending post treatment wk 12 visit, 3 without post-treatment samples).

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Overall Safety

Patients, n (%)	Total N=106
AE	75 (71)
Grade 3−4 AE	9 (8)
Serious AE	2 (2)
D/C Due to AE	2 (2)
Death	0
Grade 3 or 4 Laboratory Abnormality	19 (18)

- No patient with confirmed on-treatment HIV virologic rebound
- SAEs: Acute radial nerve palsy and left toe infection/sepsis/UTI
- Most common laboratory abnormality was elevated bilirubin in patients receiving atazanavir/ritonavir

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Adverse Events in ≥5%

Adverse Event, n (%)	Total N=106
Fatigue	26 (25)
Headache	14 (13)
Arthralgia	9 (8)
Upper Respiratory Tract Infection	9 (8)
Diarrhea	8 (8)
Insomnia	7 (7)
Nausea	7 (7)

The Majority of AEs were Mild in Severity (Grade 1 and 2)

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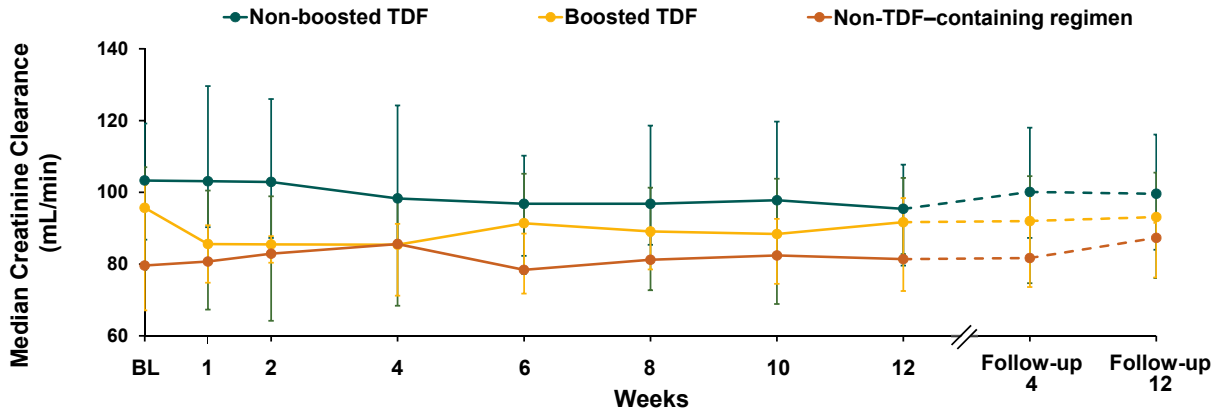
Renal Function



	BL	1	2	4	6	8	10	12	Follow-up 4	Follow-up 12
Median CL_{cr}, mL/min										
Non-boosted TDF	103			98		97		95	100	100
Boosted TDF	96			85		89		92	92	93
Non-TDF–containing regimen	80			86		81		81	82	87

Creatinine Clearance calculated using the Cockroft-Gault method; errors bars represent Q1, Q3.

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