Treatment Naïve and Treatment Experienced

HIV Coinfection

Ledipasvir-Sofosbuvir in GT-1 and HIV Coinfection
NIAID ERADICATE Trial

Osinusi A, et al. JAMA. 2015;313:1232-9.

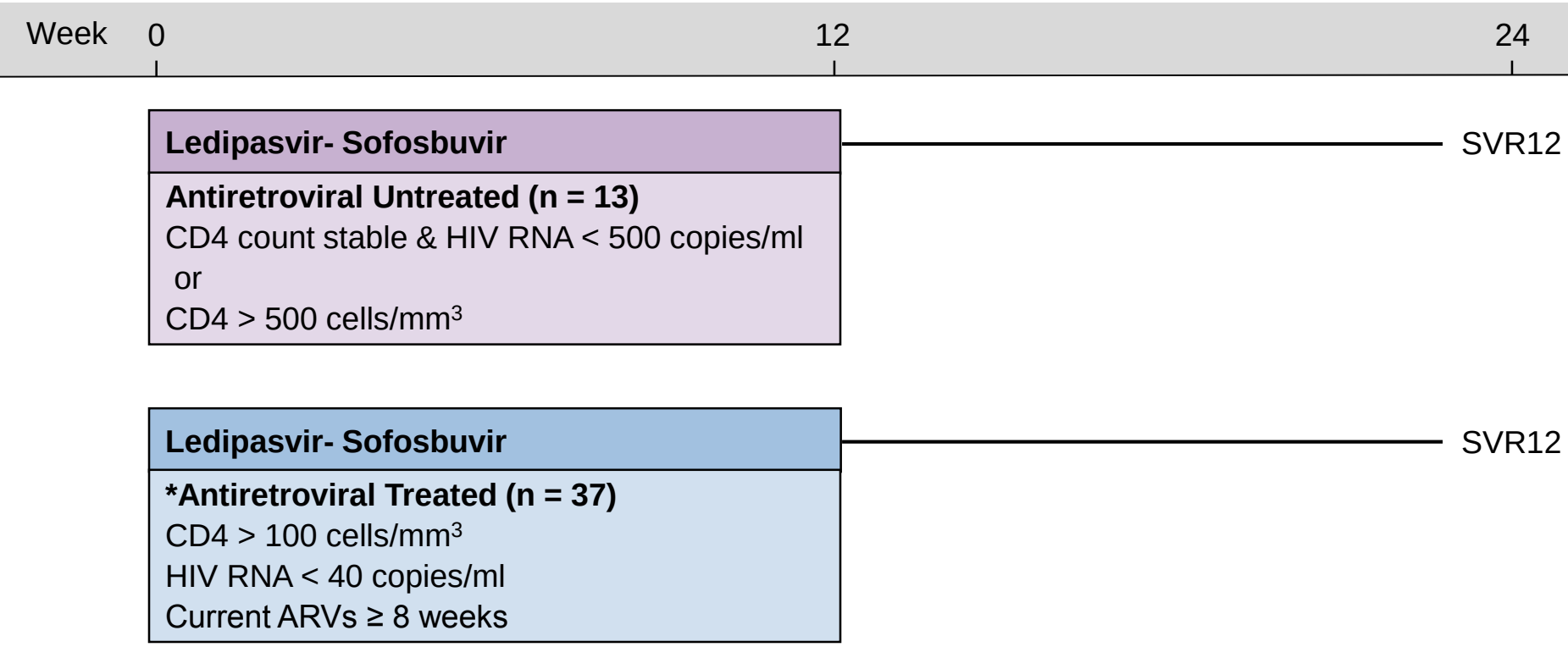
Ledipasvir-Sofosbuvir in GT1 with HIV Coinfection
NIAID ERADICATE Trial: Features

NIAID ERADICATE Trial

- **Design**: Open-label, phase 2, using fixed dose combination of ledipasvir-sofosbuvir for 12 or weeks in treatment-naïve GT 1 and HIV coinfection
- **Setting**: one center in United States
- **Entry Criteria**
  - Chronic HCV Genotype 1
  - HCV Treatment Naïve
- **Patient Characteristics (range in different treatment arms)**
  - N = 50 adult patients
  - Cohort A: Antiretroviral Untreated
  - Cohort B: Antiretroviral Treated
  - Fibrosis stage 0-3 (patients with cirrhosis excluded)
- **End-Points**: Primary = SVR12; safety and tolerability

Source: Osinusi A, et al. JAMA. 2015;313:1232-9.

Ledipasvir-Sofosbuvir in GT1 with HIV Coinfection
NIAID ERADICATE Trial: Study Design



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

***Antiretrovirals**: tenofovir-emtricitabine with one or more of following: efavirenz, rilpivirine, or raltegravir

Source: Osinusi A, et al. JAMA. 2015;313:1232-9.

Ledipasvir-Sofosbuvir in GT1 with HIV Coinfection
NIAID ERADICATE Trial: Baseline Characteristics

Baseline Characteristic	Ledipasvir-Sofosbuvir	
	ARV Untreated (n = 13)	ARV Treated (n = 37)
Mean age, years	59	58
Male, n (%)	7 (54)	30 (81)
African American, n (%)	10 (77)	23 (88)
Mean BMI, kg/m^2	26	26
GT 1a, n (%)	9 (75)	30 (81)
HAI Fibrosis Stage 3, n (%)	5 (38)	8 (22)
Mean HCV RNA, log_{10} IU/mL	6.07	5.97
Median CD4 Count (cells/mm^3)	687	576

Source: Osinusi A, et al. JAMA. 2015;313:1232-9.

Ledipasvir-Sofosbuvir in GT1 with HIV Coinfection
NIAID ERADICATE Trial: Antiretroviral Regimens

Antiretroviral Agent	Antiretroviral Received (n = 37)
Tenofovir-emtricitabine	37 (100)
Efavirenz	15 (41)
Raltegravir	10 (27)
Rilpivirine	8 (21)
Rilpivirine + Raltegravir	3 (8)
Efavirenz + Raltegravir	1 (3)

Source: Osinusi A, et al. JAMA. 2015;313:1232-9.

Sofosbuvir-Ledipasvir in GT1 with HIV Coinfection
NIAID ERADICATE Trial: Results

HCV RNA < LLOQ, %	ARV Untreated (n=13)	ARV Treated (n=37)
Week 4	100 (n =13)	100 (n=37)
Week 8	100 (n =13)	100 (n=37))
Week 12 (EOT)	100 (n =13)	100 (n=37)
SVR 4	100 (n =13)	97 (n=36)
SVR 8	100 (n =13)	97 (n=36)
SVR 12	100 (n =13)	97 (n=36)

Source: Osinusi A, et al. JAMA. 2015;313:1232-9.

Sofosbuvir-Ledipasvir in GT1 with HIV Coinfection
NIAID ERADICATE Trial: Conclusions

Conclusions and Relevance: “In this open-label, uncontrolled, pilot study enrolling patients co-infected with HCV genotype 1 and HIV, administration of an oral combination of ledipasvir and sofosbuvir for 12 weeks was associated with high rates of SVR after treatment completion. Larger studies that also include patients with cirrhosis and lower CD4 T-cell counts are required to understand if the results of this study generalize to all patients co-infected with HCV and HIV.”

Source: Osinusi A, et al. JAMA. 2015;313:1232-9.

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