

Treatment Naïve and Treatment Experienced

# Sofosbuvir-Ledipasvir +/- Ribavirin in GT-1 LONESTAR Trial

Source: Lawitz E, et al. Lancet. 2014;383:515-23.

# Ledipasvir-Sofosbuvir +/- Ribavirin in Naïve & Experienced GT1 LONESTAR Trial: Features

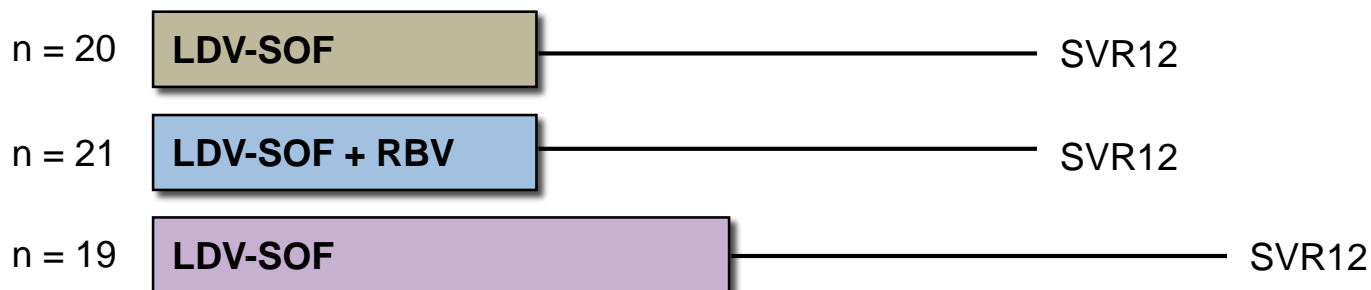
## LONESTAR Trial

- **Design:** Open-label, phase 2, using fixed dose combination of ledipasvir-sofosbuvir +/- ribavirin in treatment-naïve and treatment-experienced GT 1
- **Setting:** one center in USA (San Antonio, Texas)
- **Entry Criteria**
  - Chronic HCV Genotype 1
  - Cohort A: Treatment-naïve
  - Cohort B: Prior virologic failure with protease inhibitor regimen
- **Patient Characteristics (range in different treatment arms)**
  - N = 100 adult patients
  - Treatment-Naive: none with cirrhosis
  - Previously Treated: approximately 55% with cirrhosis
  - Previously Treated: approximately 2/3 non-responders and 1/3 relapsers
  - IL28B Genotype: non-CC (range of 67-95%)
- **End-Points:** Primary = SVR12; safety and tolerability

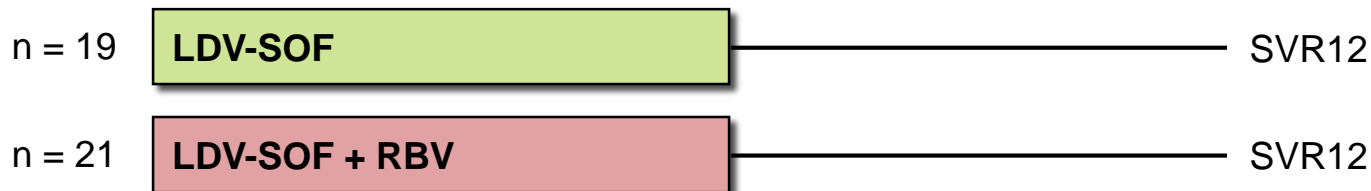
# Ledipasvir-Sofosbuvir +/- Ribavirin in Naïve & Experienced GT1 LONESTAR: Study Design

Week 0 8 12 20 24

## Cohort A Naïve n=60



## Cohort B Experienced n=40



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

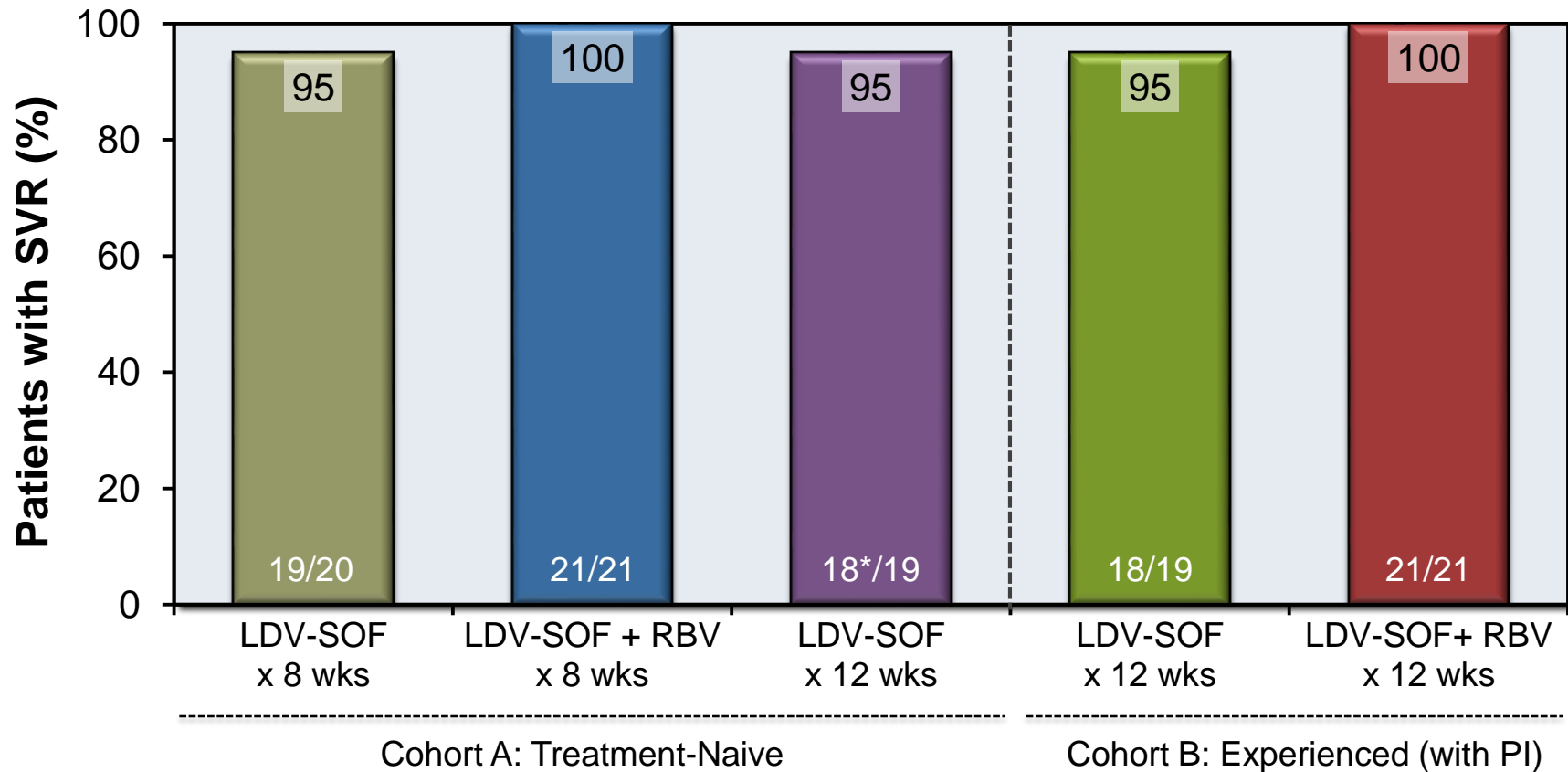
### Drug Dosing

Ledipasvir-Sofosbuvir: 90/400 mg fixed dose combination one pill once daily

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

# Ledipasvir-Sofosbuvir +/- Ribavirin in Naïve & Experienced GT1 LONESTAR Trial: Results

## LONESTAR: SVR 12, by Cohort and Treatment Regimen



\*One patient lost to follow-up; LDV-SOF = ledipasvir-sofosbuvir; RBV = ribavirin; PI = protease inhibitor

# Ledipasvir-Sofosbuvir +/- Ribavirin in Naïve & Experienced GT1 LONESTAR Trial: Adverse Events

Adverse Event (AE)	Cohort A			Cohort B	
	LDV-SOF x 8 weeks (n=20)	LDV-SOF + RBV x 8 weeks (n=21)	LDV-SOF x 12 weeks (n=19)	LDV-SOF x 12 weeks (n=19)	LDV-SOF + RBV x 12 weeks (n=21)
Serious AE	0 (0%)	1 (5%)	1 (5%)	1 (5%)	1 (5%)
Nausea	2 (10%)	2 (10%)	1 (5%)	0 (0%)	4 (19%)
Anemia	0 (0%)	2 (10%)	0 (0%)	0 (0%)	6 (29%)
Upper RTI	2 (10%)	0 (0%)	1 (5%)	1 (5%)	4 (19%)
Headache	2 (10%)	3 (14%)	0 (0%)	1 (5%)	1 (5%)
Abdominal pain	1 (5%)	1 (5%)	1 (5%)	0 (0%)	1 (5%)
Bronchitis	1 (5%)	1 (5%)	0 (0%)	1 (5%)	1 (5%)
Back pain	1 (5%)	1 (5%)	1 (5%)	1 (5%)	0 (0%)
Decreased appetite	0 (0%)	2 (10%)	0 (0%)	1 (5%)	0 (0%)
Dermatitis	1 (5%)	0 (0%)	0 (0%)	0 (0%)	2 (10%)
Muscle spasms	1 (5%)	0 (0%)	0 (0%)	0 (0%)	2 (10%)

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# Ledipasvir-Sofosbuvir +/- Ribavirin in Naïve & Experienced GT1 LONESTAR Trial: Conclusion

**Interpretation:** “These findings suggest that the fixed-dose combination of sofosbuvir-ledipasvir alone or with ribavirin has the potential to cure most patients with genotype-1 HCV, irrespective of treatment history or the presence of compensated cirrhosis. Further clinical trials are needed to establish the best treatment duration and to further assess the contribution of ribavirin.”

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

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[www.hepatitisc.uw.edu](http://www.hepatitisc.uw.edu)

Hepatitis Web Study  
<http://depts.washington.edu/hepstudy/>

Funded by a grant from the Centers for Disease Control and Prevention.