Treatment Naïve (unfavorable baseline treatment characteristics)

# Ledipasvir-Sofosbuvir +/- 3rd DAA in HCV Genotype 1

# NIH SYNERGY

Kohli A, et al. 21st CROI. 2014:Abstract 27LB.

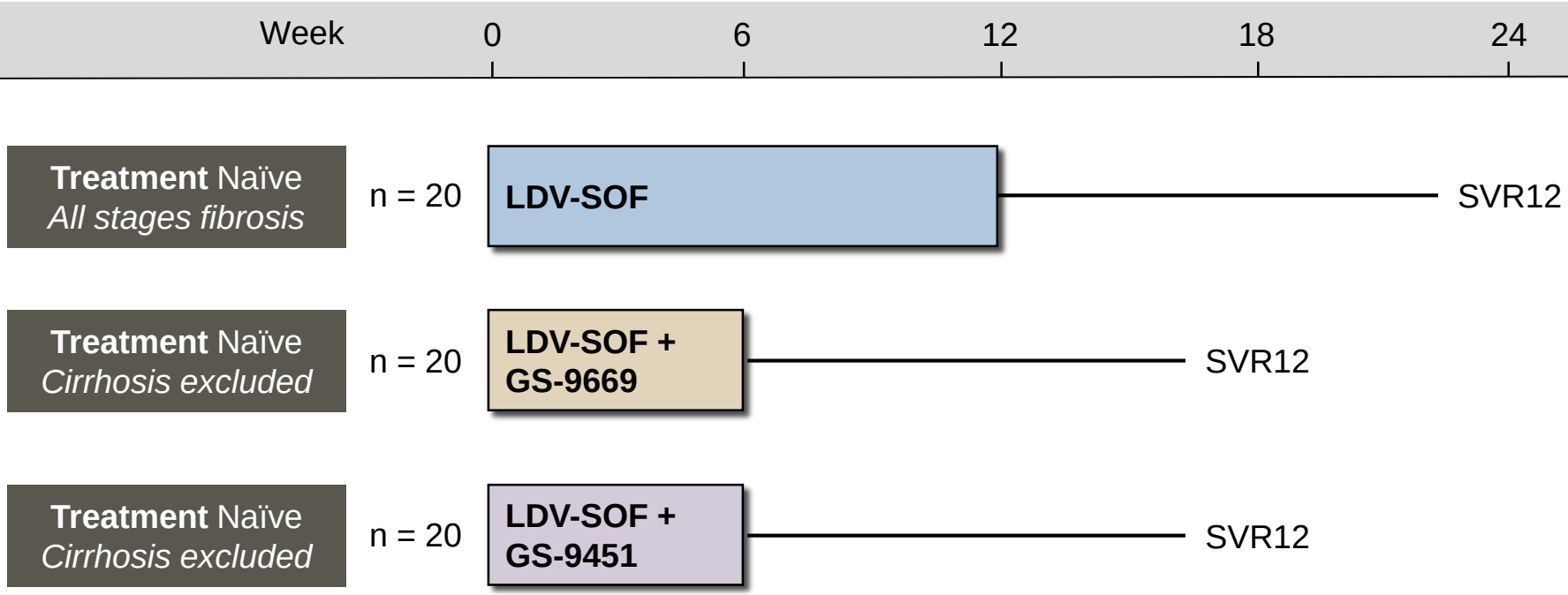
# Ledipasvir-Sofosbuvir +/- [GS-9669 or GS-9451] in Naïve GT1
## NIH SYNERGY Trial: Features

**NIH SYNERGY Trial**

- **Design**: Open-label, phase 2, using fixed dose ledipasvir-sofosbuvir alone or in combination with either GS-9669 (non-nucleoside NS5B inhibitor) or GS-9451 (NS3/4A protease inhibitor) in treatment-naïve GT 1
- **Setting**: single site, United States
- **Entry Criteria**
  - Chronic HCV Genotype 1
  - Treatment naive
  - HCV RNA > 50,000 IU/mL
- **Patient Characteristics**
  - N = 60 adult patients
  - Demographics: 72% male; 88% black
  - IL28B Genotype: 80% with non-CC
  - Liver Fibrosis: 70% Knodell HAI Fibrosis score 0-2
- **Primary End-Point**: SVR12

**Source: Kohli A, et al. 21st CROI. 2014:Abstract 27LB.**

# Ledipasvir-Sofosbuvir +/- [GS-9669 or GS-9451] in Naïve GT1 NIH SYNERGY Trial: Features




**Abbreviations**: LDV-SOF= ledipasvir-sofosbuvir

**Drug Dosing**

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

GS-9669: 500 mg once daily

GS-9451: 80 mg once daily

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# Ledipasvir-Sofosbuvir +/- [GS-9669 or GS-9451] in Naïve GT1
## NIH SYNERGY Trial: Participants

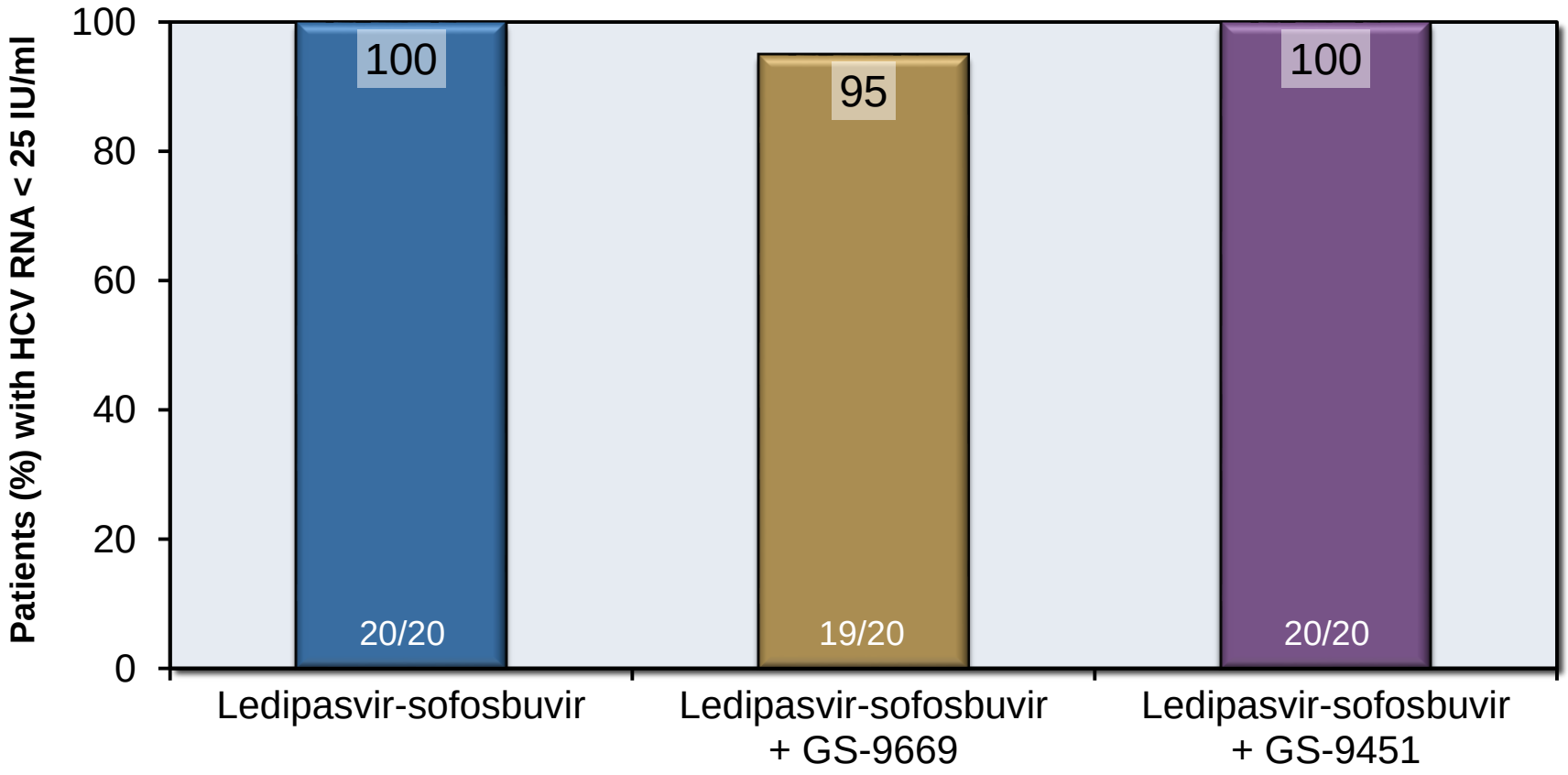
| Baseline Characteristic | LDV-SOF x 12 weeks (n=20) | LDV-SOF + GS-9669 x 6 weeks (n=20) | LDV-SOF + GS-9451 x 6 weeks (n=20) |
|---|---|---|---|
| Age, mean | 57 | 54 | 54 |
| Male, % | 70 | 65 | 80 |
| Black, % | 80 | 95 | 90 |
| HCV genotype, % | | | |
| 1A | 55 | 70 | 85 |
| 1B | 45 | 30 | 15 |
| IL28B CT/TT, % | 75 | 90 | 75 |
| Advanced fibrosis, % | | | |
| Knodell score 3 | 25 | 25 | 25 |
| Knodell score 4 | 15 | 0 | 0 |

**Source: Kohli A, et al. 21st CROI. 2014:Abstract 27LB.**

Hepatitis web study

# Ledipasvir-Sofosbuvir +/- [GS-9669 or GS-9451] in Naïve GT1 NIH SYNERGY Trial: Features

## NIH SYNERGY: SVR 12 by Treatment Regimen




**Source: Kohli A, et al. 21st CROI. 2014:Abstract 27LB.**

Hepatitis web study

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