Treatment Naïve and Treatment Experienced

Ledipasvir-Sofosbuvir in HCV Genotype 4

NIAID SYNERGY (Genotype 4)

Kohli A, et al. Lancet Infect Dis. 2015:15:1049-54.

Ledipasvir-Sofosbuvir in Genotype 4
NIAID SYNERGY (GT4) Trial: Features

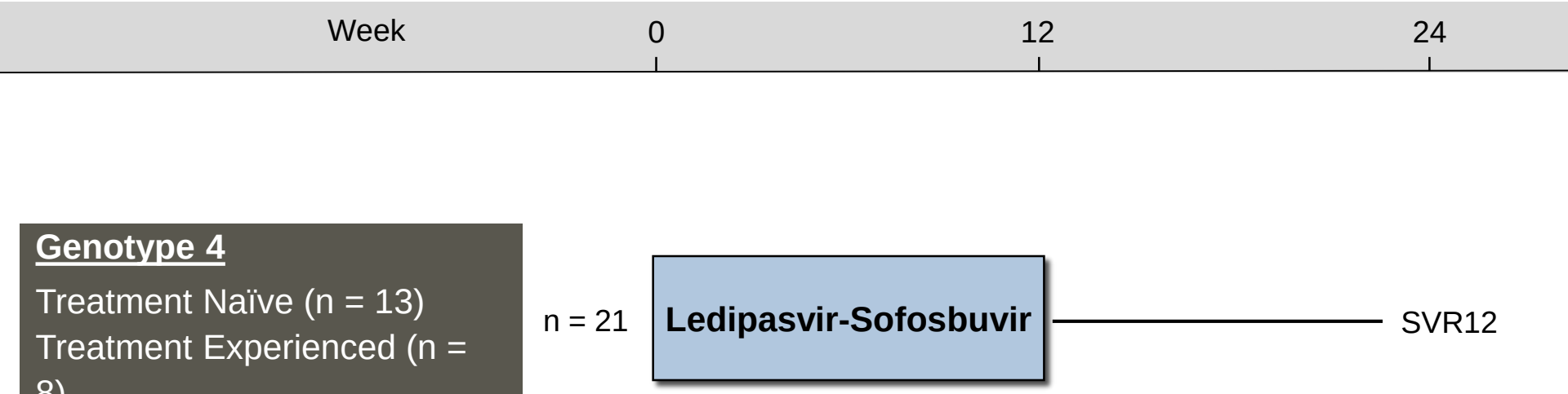
NIAID SYNERGY Trial

- **Design**: Open-label, phase 2a trial using fixed dose ledipasvir-sofosbuvir for treatment-naïve and interferon treatment-experienced patients with chronic HCV genotype 4
- **Setting**: single center (Clinical Center at NIH, United States)
- **Entry Criteria**
  - 18 years of age or older
  - Chronic HCV Genotype 4
  - Treatment naïve or prior interferon treatment failure
  - HCV RNA ≥2,000 IU/mL
  - Exclusions: HBV, HIV, or decompensated liver disease
- **Primary End-Point**: SVR12

Source: Kohli A, et al. Lancet Infect Dis. 2015:15:1049-54.

Hepatitis web study

Ledipasvir-Sofosbuvir in Genotype 4
NIAID SYNERGY (GT4) Trial: Features



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

Source: Kohli A, et al. Lancet Infect Dis. 2015:15:1049-54.

Hepatitis web study

Ledipasvir-Sofosbuvir in Genotype 4
NIAID SYNERGY (GT4) Trial: Key Baseline Characteristics

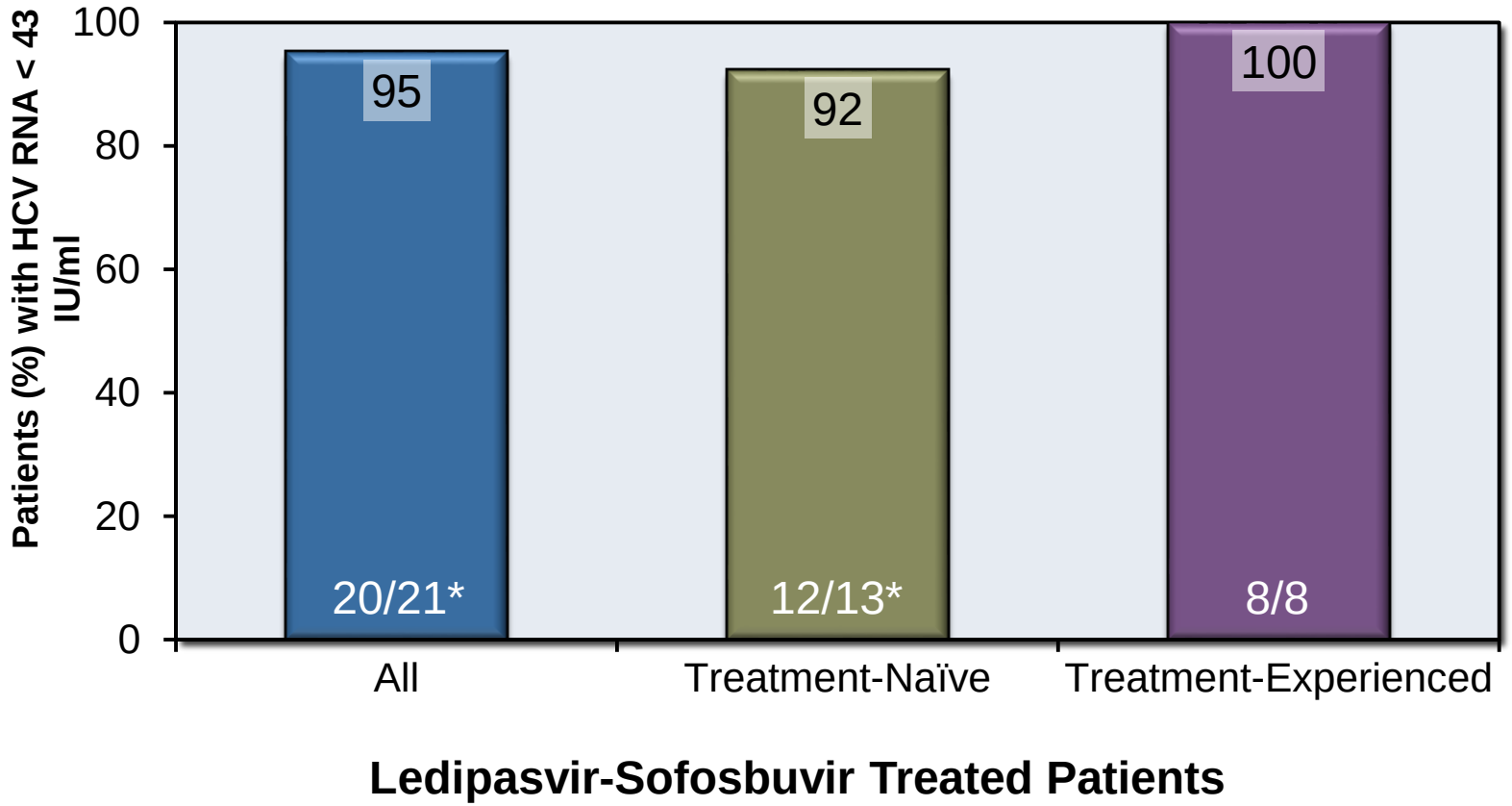
- Sex: Male 67%
- Race: 43% Black; 52% White; 5% Native American
- Country of Origin: 29% Egypt; 24% United States
- Treatment Experience: 62% naïve; 38% experienced
- HCV RNA > 800,000 IU/mL: 62%

Source: Kohli A, et al. Lancet Infect Dis. 2015:15:1049-54.

Hepatitis web study

Ledipasvir-Sofosbuvir in Genotype 4
NIAID SYNERGY (GT4) Trial: Results

NIH SYNERGY: SVR 12, Intent to Treat Analysis



*1 patient did not complete 12 weeks of treatment due to drug non-adherence

Source: Kohli A, et al. Lancet Infect Dis. 2015:15:1049-54.

Hepatitis web study

Ledipasvir-Sofosbuvir in Genotype 4
NIAID SYNERGY (GT4) Trial: Interpretation

Interpretation: “Ledipasvir and sofosbuvir treatment for 12 weeks was well tolerated by patients with HCV genotype 4 and resulted in 100% SVR for all patients who received all 12 weeks of study drugs, irrespective of previous treatment status and underlying liver fibrosis. This is the first report of a single-pill, all-oral, interferon-free, ribavirin-free treatment for patients with HCV genotype 4.”

Source: Kohli A, et al. Lancet Infect Dis. 2015:15:1049-54.

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/

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

Hepatitis web study