

Treatment Naïve and Treatment Experienced

Ledipasvir-Sofosbuvir +/- Ribavirin in HCV Genotype 3 or 6 New Zealand Genotype 3 and 6 Study

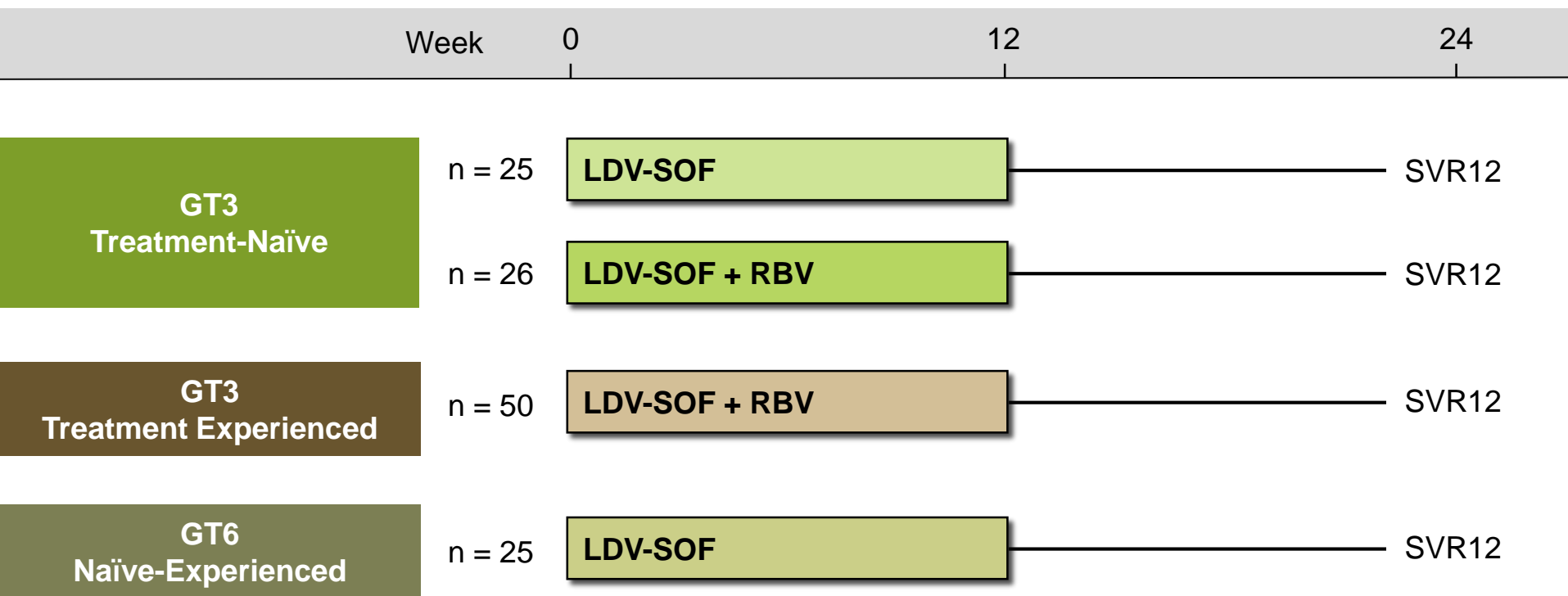
Gane EJ, et al. Gastroenterology. 2015 August 7. [Epub ahead of print]

Ledipasvir-Sofosbuvir +/- Ribavirin in HCV GT 3 or 6 New Zealand GT 3 & 6 Study: Features

ELECTRON 2 Trial

- **Design:** Open-label, phase 2, using fixed-dose combination of ledipasvir-sofosbuvir +/- ribavirin in treatment-naïve GT3, ledipasvir-sofosbuvir + ribavirin in treatment-experienced genotype 3, and ledipasvir-sofosbuvir in treatment-naïve or treatment-experienced patients with genotype 6
- **Setting:** Two hepatitis treatment centers in New Zealand
- **Entry Criteria**
 - Chronic HCV (n=126)
 - 18 years or older
 - HCV RNA > 10,000 IU/mL
 - Failed prior therapy with sequential PEG + RBV and PEG + RBV + PI
 - Compensated cirrhosis by: (a) biopsy, (b) FibroScan >12.5 kPa, or (c) FibroTest (FibroSURE) >0.75 and APRI >2
 - Excluded if evidence of hepatic decompensation, HCC, HIV, or HBV
- **Primary End-Point:** SVR12

Ledipasvir-Sofosbuvir +/- Ribavirin in HCV GT 3 or 6 New Zealand GT 3 & 6 Study: Study Design



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

Drug Dosing

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

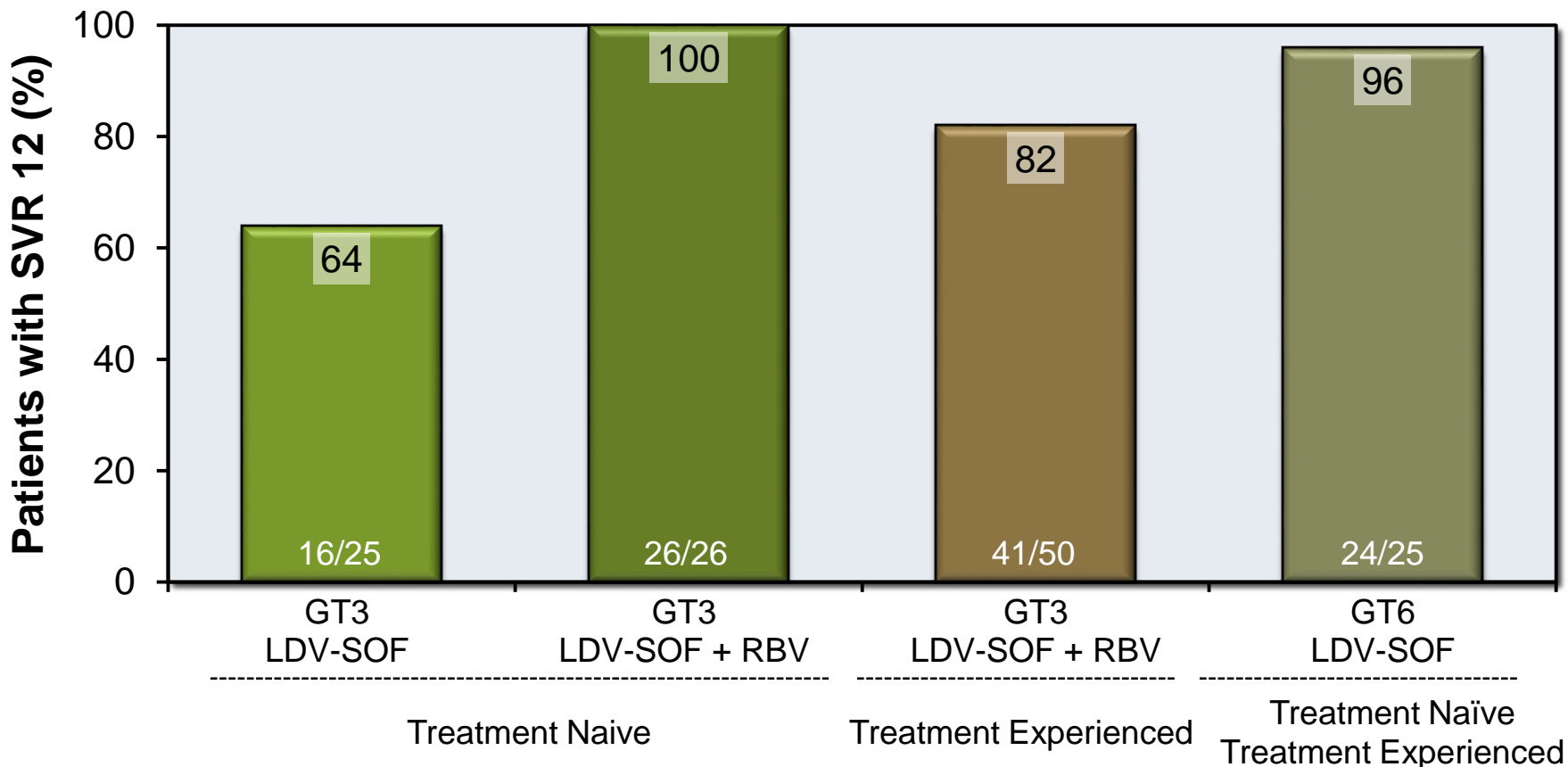
Ribavirin (weight-based and divided bid): 1000 mg/day if < 75 kg or 1200 mg/day if ≥ 75 kg

Ledipasvir-Sofosbuvir +/- Ribavirin in HCV GT 3 or 6 New Zealand GT 3 & 6 Study: Baseline Characteristics

	GT 3 Naïve		GT 3 Experienced	GT 6 Naïve/Experienced
	LDV-SOF n=25	LDV-SOF + RBV n=26	LDV-SOF + RBV n=50	LDV-SOF n=25
Mean age, years	43	48	52	51
Male, n (%)	13 (52)	11 (42)	39 (78)	16 (64)
White, n (%)	22 (88)	23 (88)	40 (80)	4 (16)
BMI <30 kg/m ² , n (%)	19 (76)	18 (69)	42 (84)	23 (92)
Cirrhosis, n (%)	3 (12)	5 (19)	0	20 (100)
IL28B CC, n (%)	9 (36)	15 (58)	4 (21)	7 (35)
Prior Treatment, n (%)	0	0	50 (100)	2 (8)
Cirrhosis, n (%)	4 (16)	6 (23)	22 (44)	2 (8)
Mean HCV RNA, log ₁₀ IU/mL	6.3	6.3	6.3	6.7

Ledipasvir-Sofosbuvir +/- Ribavirin in HCV GT 3 or 6 New Zealand GT 3 & 6 Study: Results

SVR 12, by GT and Treatment Regimen



LDV-SOF = ledipasvir-sofosbuvir; RBV = ribavirin

Ledipasvir-Sofosbuvir +/- Ribavirin in HCV GT 3 or 6 New Zealand GT 3 & 6 Study: Conclusions

Conclusions: “In an uncontrolled, open-label trial, high rates of SVR12 were achieved by patients with HCV genotype 3 infection who received 12 weeks of ledipasvir-sofosbuvir plus ribavirin, and by patients with HCV genotype 6 infection who received 12 weeks of sofosbuvir-ledipasvir without ribavirin. Current guidelines do not recommend the use of ledipasvir-sofosbuvir, with or without ribavirin, in patients with HCV genotype 3 infection.”

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.