Phase 3

Treatment Naïve

Ledipasvir-Sofosbuvir +/- Ribavirin for 8 or 12 weeks in HCV GT1 ION-3

Source: Kowdley K, et al. N Engl J Med. 2014;370:1879-88.

Hepatitis web study

Ledipasvir-Sofosbuvir for 8 or 12 Weeks in Treatment-Naïve HCV GT 1

ION-3 Study: Features

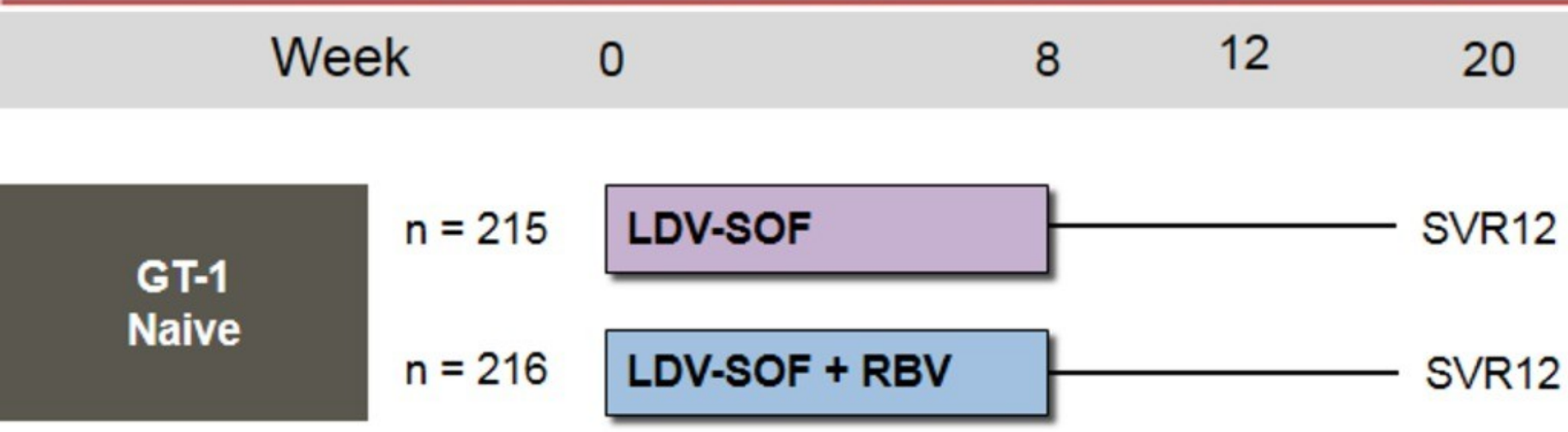
ION-3 Trial

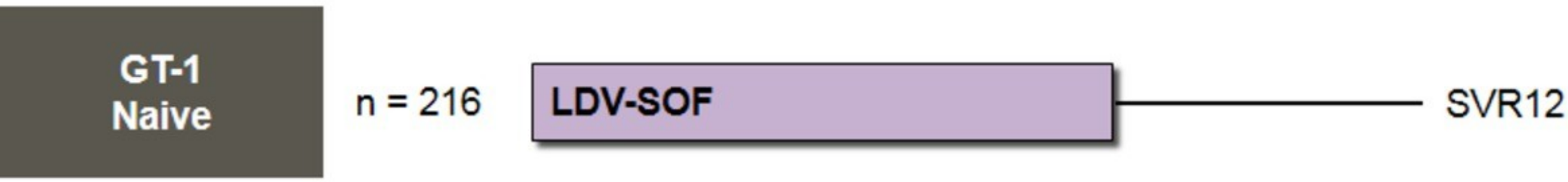
- **Design**: Open-label, randomized, phase 3, using fixed-dose combination of ledipasvir-sofosbuvir +/- ribavirin in treatment-naïve patients with GT1 HCV to explore feasibility of shortening treatment duration from 12 weeks to 8 weeks.
- **Setting**: 58 sites in United States
- **Entry Criteria**
  - Chronic HCV Genotype 1 (n = 647)
  - 18 years or older
  - No prior HCV treatment
  - Patients with cirrhosis were excluded
- **Primary End-Point**: SVR12

Source: Kowdley, K, et al. N Engl J Med. 2014;370:1879-88.

Ledipasvir-Sofosbuvir for 8 or 12 Weeks in Treatment-Naïve HCV GT 1

ION-3 Study: Study Design





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

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

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Ledipasvir-Sofosbuvir for 8 or 12 Weeks in Treatment-Naïve HCV GT 1

ION-3 Study: Baseline Characteristics

	8 Weeks		12 Week-Treatment
	LDV-SOF n=215	**LDV-SOF + RBV** n=216	**LDV-SOF** n=216
Mean age, y (range)	53 (22–75)	51 (21–71)	53 (20–71)
BMI, kg/m^2 mean (range)	28 (18–43)	28 (18–56)	28 (19–45)
Male sex, n (%)	130 (60)	117 (54)	128 (59)
Race			
White, n (%)	164 (76)	176 (81)	177 (82)
Black, n (%)	45 (21)	36 (17)	42 (19)
Asian, n (%)	6 (3)	4 (2)	7 (3)
HCV Genotype			
1a, n (%)	171 (80)	172(68)	172 (80)
1b, n (%)	43 (20)	44 (20)	44 (20)
IL28B CC, n (%)	56 (26)	60 (28)	56 (26)
F3 fibrosis, n (%)	29 (13)	28 (13)	29 (13)
HCV RNA, $\log_{10}$ IU/ml, mean	6.5	6.4	6.4

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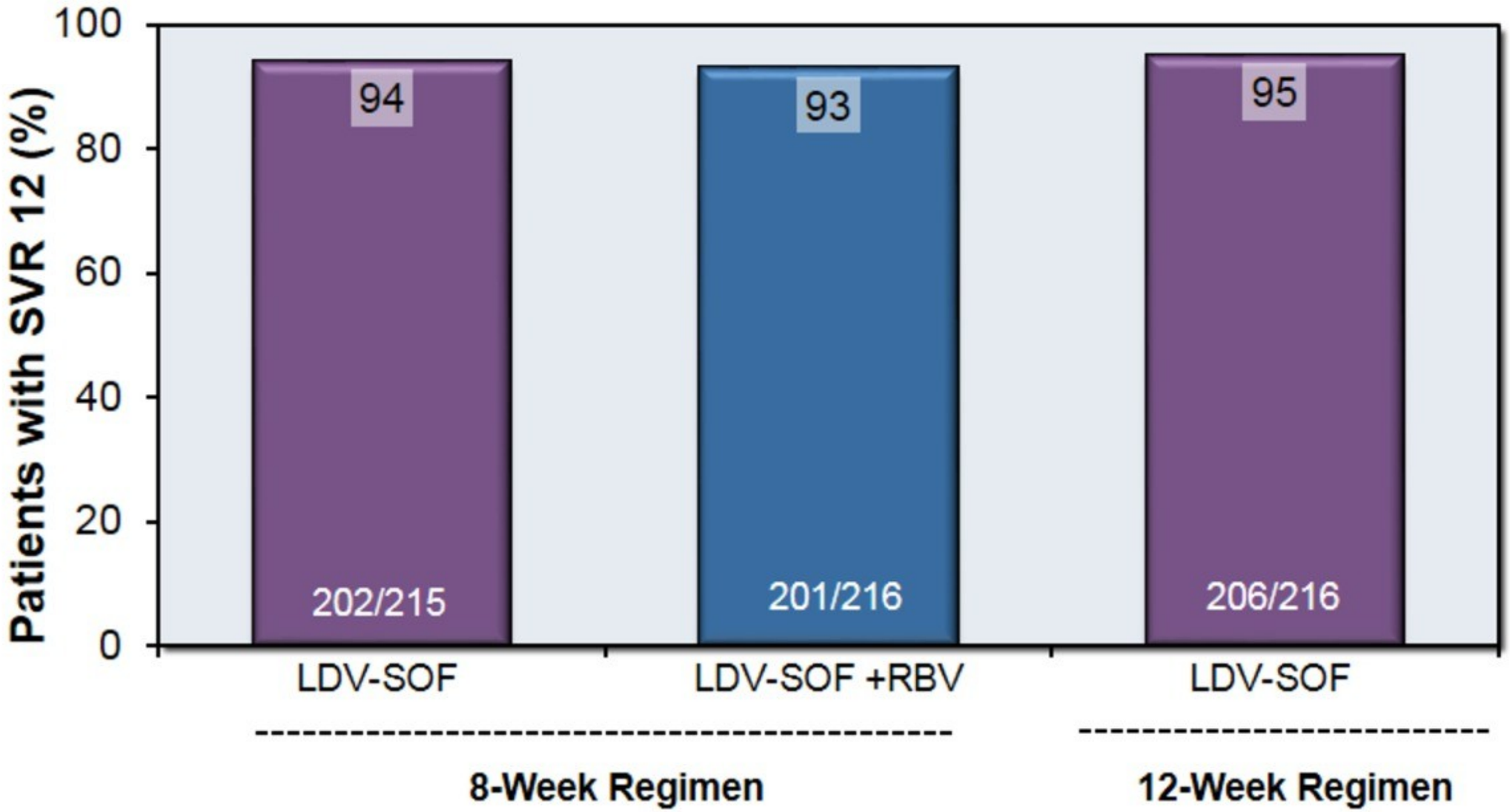
ION-3 Study: Results

ION-3: SVR 12 by Treatment Duration and Regimen



LDV= ledipasvir; SOF = sofosbuvir; RBV = ribavirin

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Ledipasvir-Sofosbuvir for 8 or 12 Weeks in Treatment-Naïve HCV GT 1

ION-3 Study: Conclusions

Conclusions: "Ledipasvir-sofosbuvir for 8 weeks was associated with a high rate of sustained virologic response among previously untreated patients with HCV genotype 1 infection without cirrhosis. No additional benefit was associated with the inclusion of ribavirin in the regimen or with extension of the duration of treatment to 12 weeks."

Source: Kowdley, K, et al. N Engl J Med. 2014;370:1879-88.

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