

# Ledipasvir-Sofosbuvir in GT1 or GT4 and HIV Coinfection ION-4

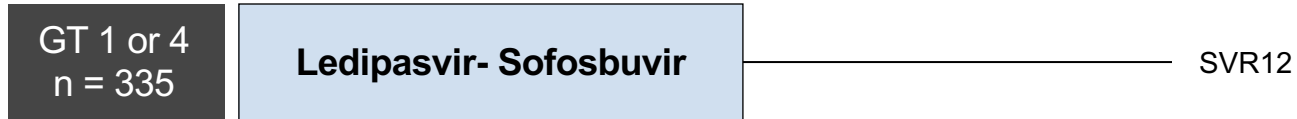
# Ledipasvir-Sofosbuvir in GT1 or GT4 with HIV Coinfection

## ION-4 Trial: Features

- **Design:** Open-label, single group, phase 3 trial, using ledipasvir-sofosbuvir for 12 weeks in treatment-naïve or treatment-experienced patients with GT 1 or 4 and HIV coinfection
- **Setting:** multicenter in United States, Canada, New Zealand
- **Entry Criteria**
  - Chronic HCV Genotype 1 or 4
  - Treatment-naïve or treatment-experienced
  - Noncirrhotic or compensated cirrhosis
  - Platelet count  $>50,000/\text{mm}^3$ , hemoglobin  $\geq 10$  mg/dL, CrCl  $\geq 60$  mL/min
  - Stable ARV with HIV RNA  $<50$  mL and CD4 count  $>100$  cells/ $\text{mm}^3$
  - ARV Regimens: tenofovir DF-emtricitabine + [efavirenz, rilpivirine, or raltegravir]
- **Primary End Point:** SVR12

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## ION-4 Trial: Study Design



**Drug Dosing:** Ledipasvir-sofosbuvir (90/400 mg): fixed dose combination; one pill once daily  
**Antiretrovirals allowed:** tenofovir DF-emtricitabine plus either efavirenz, rilpivirine, or raltegravir

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## ION-4 Trial: Baseline Characteristics

Baseline Characteristic	Ledipasvir-Sofosbuvir (n = 335)
Mean age, years	52
Male, n (%)	276 (82)
African American, n (%)	115 (34)
Hispanic or Latino, n (%)	56 (17)
Mean BMI, kg/m <sup>2</sup>	26
IL28B CC, n (%)	81 (24)
GT 1 (%)	327 (98)
HCV treatment experienced, n (%)	185 (55)
Cirrhosis, n (%)	67 (20)
Mean HCV RNA, log <sub>10</sub> IU/mL	6.7 ± 0.6
Median CD4 Count, cells/mm <sup>3</sup> (range)	628 (100-2069)

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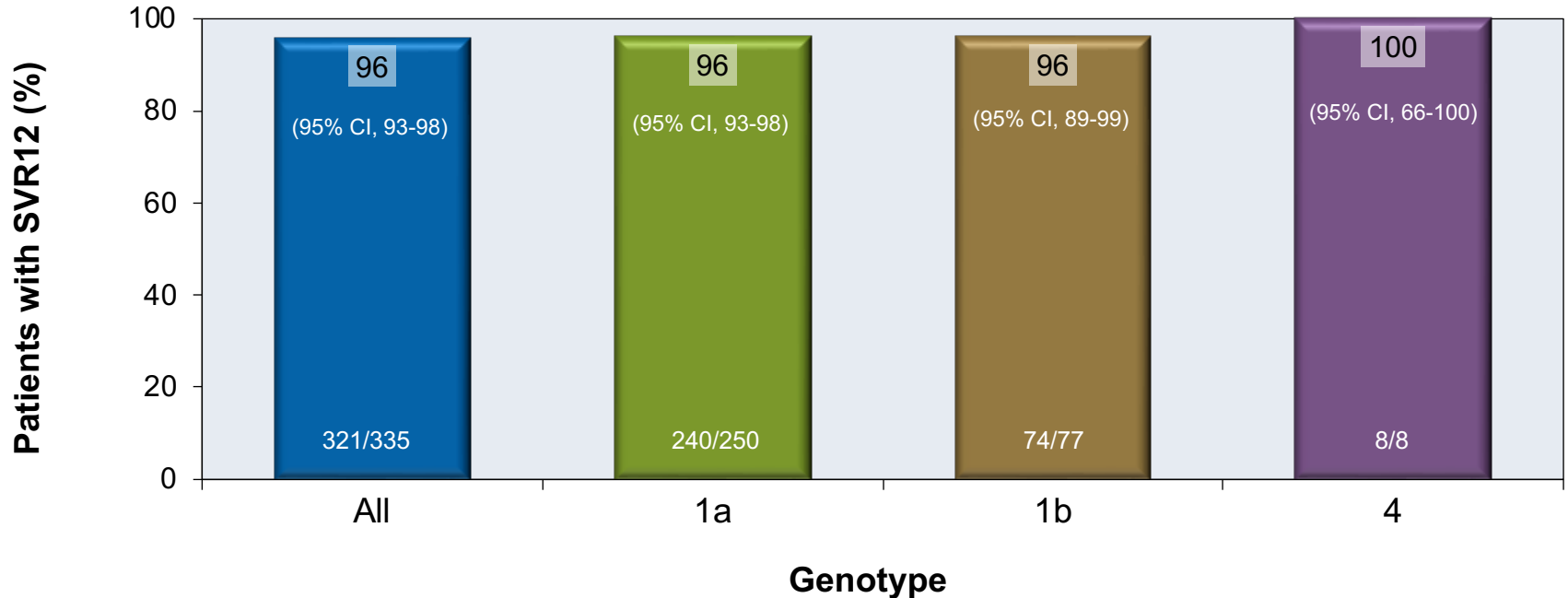
## ION-4 Trial: Antiretroviral Regimens

ION-4: HIV Antiretroviral Regimen	
Antiretroviral Agent	Antiretroviral Received (n = 335)
Tenofovir DF-emtricitabine-efavirenz	160 (48)
Tenofovir DF-emtricitabine-rilpivirine	29 (9)
Tenofovir DF-emtricitabine + Raltegravir	146 (44)

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## ION-4 Trial: Results

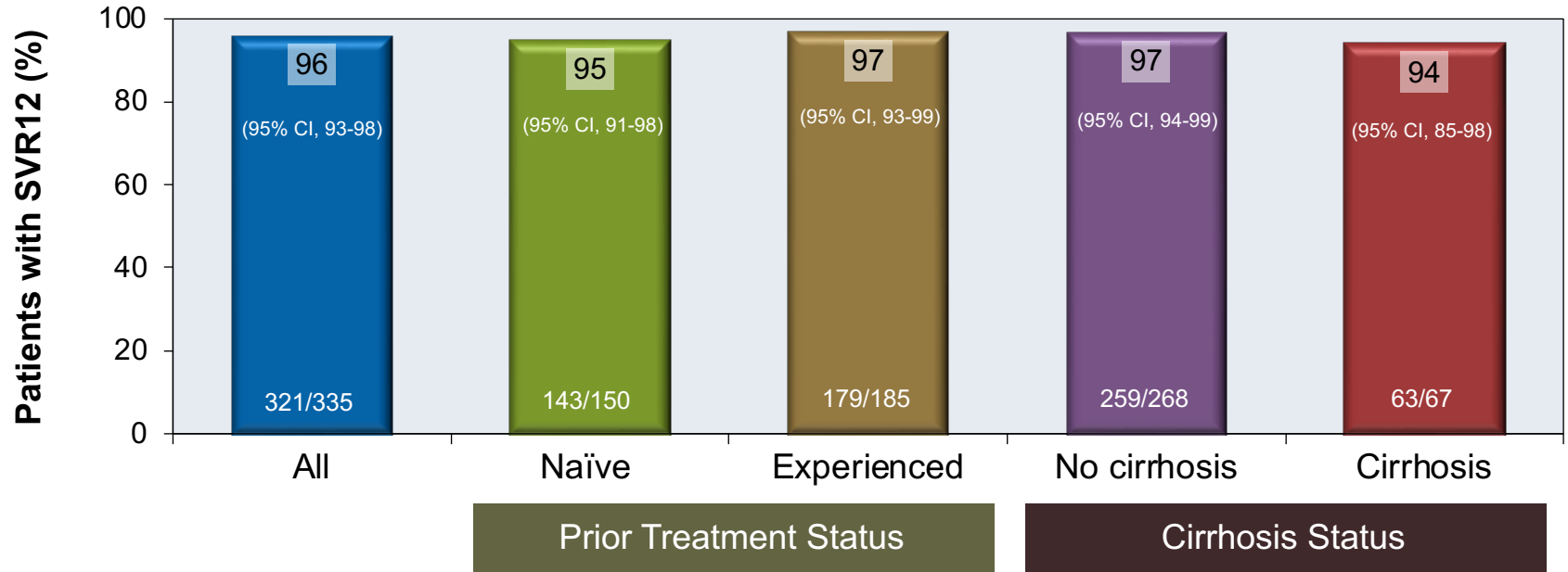
### ION-4: SVR12 Results by Genotype



# Ledipasvir-Sofosbuvir in GT1 or GT4 with HIV Coinfection

## ION-4 Trial: Results

### ION-4: SVR12 Results by Prior Treatment Status and Cirrhosis Status



# Ledipasvir-Sofosbuvir in GT1 or GT4 with HIV Coinfection

## ION-4 Trial: Adverse Effects

Event	Ledipasvir-Sofosbuvir (n = 335)
Discontinuation due to adverse event	0
Grade 3-4 Adverse Event	14 (4%)
Serious Adverse Event	8 (2%)
Headache	83 (25%)
Fatigue	71 (21%)
Diarrhea	36 (11%)
Nausea	33 (10%)
Arthralgia	22 (7%)
Upper respiratory tract infection	18 (5%)
Vomiting	14 (4%)
Muscle spasms	11 (3%)



# Ledipasvir-Sofosbuvir in GT1 or GT4 with HIV Coinfection ION-4 Trial: Conclusions

**Conclusions:** “Ledipasvir and sofosbuvir for 12 weeks provided high rates of sustained virologic response in patients coinfecting with HIV-1 and HCV genotype 1 or 4.”

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