Elbasvir-Grazoprevir in HCV and HIV Coinfection, GT 1, 4 or 6

C-EDGE CO-INFECTION

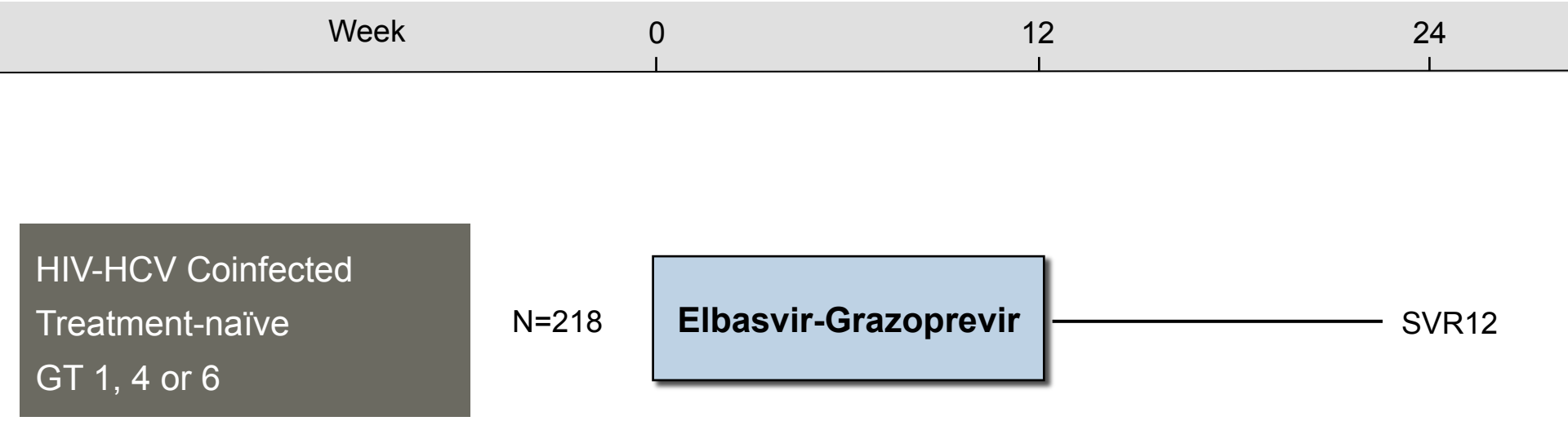
Elbasvir-Grazoprevir in HCV-HIV Coinfection GT 1, 4 or 6
C-EDGE CO-INFECTION: Study Features

C-EDGE Trial

- **Design**: Prospective, open-label, single-arm study examining the safety and efficacy of a fixed-dose combination of elbasvir-grazoprevir for 12 weeks in treatment-naïve patients with chronic HCV genotype 1, 4, or 6 and HIV coinfection.
- **Entry Criteria**
  - Chronic HCV Genotype 1, 4, or 6
  - 18 years or older
  - HCV RNA ≥10,000 IU/mL
  - No prior treatment
  - Compensated cirrhosis permitted
  - HIV infection
- **Primary End-Point**: SVR12

Source: Rockstroh JK, et al. Lancet HIV. 2015;2:e319-27.

Elbasvir-Grazoprevir in HCV-HIV Coinfection GT 1, 4 or 6
C-EDGE CO-INFECTION: Study Design



Drug Dosing
Elbasvir-grazoprevir (50/100 mg): fixed dose combination; one pill once daily

Source: Rockstroh JK, et al. Lancet HIV. 2015;2:e319-27.

Elbasvir-Grazoprevir in HCV-HIV Coinfection GT 1, 4 or 6
C-EDGE CO-INFECTION: Participants

Baseline Characteristic	Elbasvir-Grazoprevir (N=218)
Age, mean	49
Male, n (%)	183 (84%)
Race, n (%) White Black or African-American Other	 167 (77%) 38 (17%) 13 (6%)
HCV genotype, n (%) 1a 1b 4 6	 144 (66%) 44 (20%) 28 (13%) 2 (1%)
Fibrosis stage, n (%) F0-2 F3 F4	 160 (73%) 23 (11%) 35 (16%)
Mean baseline HCV RNA, $\log_{10}$ IU/ml	6.03

Source: Rockstroh JK, et al. Lancet HIV. 2015;2:e319-27.

Elbasvir-Grazoprevir in HCV-HIV Coinfection GT 1, 4 or 6
C-EDGE CO-INFECTION: Participants

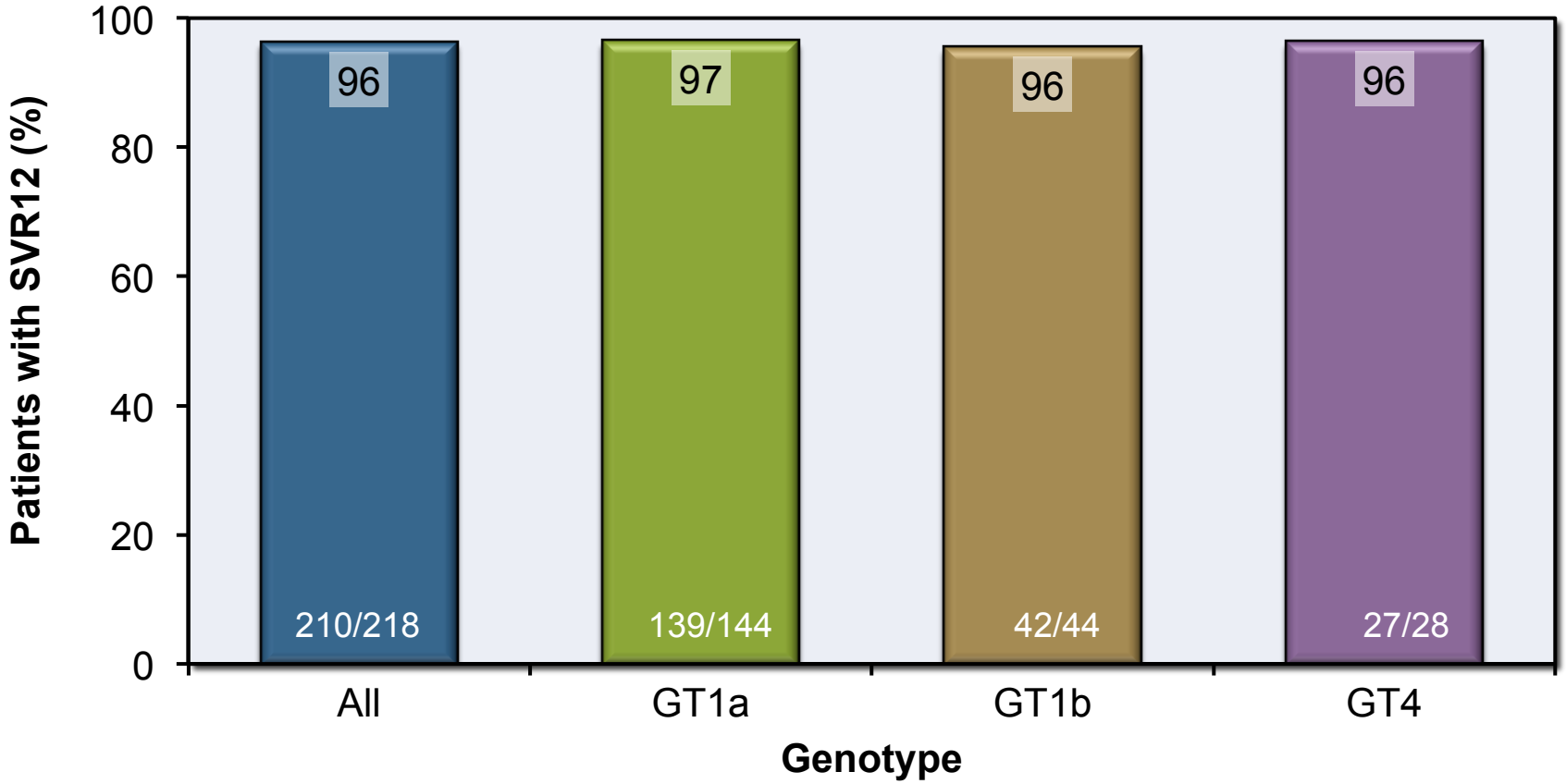
HIV Characteristics	Elbasvir-Grazoprevir (N=218)
Median CD4 cell count, (IQR)	568 (424-766)
ART Status	
On ART with undetectable HIV RNA	211 (97%)
ART naïve	7 (3%)
ART nucleos(t)ide pair	
Abacavir-containing	47 (22%)
Tenofovir-containing	164 (75%)
None	7 (3%)
ART Third Agent	
Raltegravir	113 (52%)
Dolutegravir	59 (27%)
Rilpivirine	38 (17%)
None	8 (4%)

IQR = interquartile range; ART = antiretroviral therapy

Source: Rockstroh JK, et al. Lancet HIV. 2015;2:e319-27.

Elbasvir-Grazoprevir in HCV-HIV Coinfection GT 1, 4 or 6
C-EDGE CO-INFECTION: Results

C-EDGE CO-INFECTION: SVR12 Results by Genotype



Overall SVR12 results includes the 2 patients with GT 6, who both achieved SVR12.

Source: Rockstroh JK, et al. Lancet HIV. 2015;2:e319-27.

Elbasvir-Grazoprevir in HCV-HIV Coinfection GT 1, 4 or 6
C-EDGE CO-INFECTION: Adverse Events

Adverse Event (AE), n (%)	Elbasvir-Grazoprevir (N=218)	
Discontinuation due to AE	0	
Serious AEs	2 (1%)	
Deaths	0	
Any AE in >5% of patients		
Fatigue	29 (13%)	
Headache	27 (12%)	
Nausea	20 (9%)	
Upper respiratory tract infection	18 (8%)	
Diarrhea	16 (7%)	
Insomnia	15 (7%)	
Grade 3 or 4 laboratory abnormality	Grade 3	Grade 4
Total bilirubin	1 (<1%)	0
ALT elevation	3 (1%)	2 (1%)
AST elevation	0	1 (<1%)
Hemoglobin	0	0

Source: Rockstroh JK, et al. Lancet HIV. 2015;2:e319-27.

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Elbasvir-Grazoprevir in HCV-HIV Coinfection GT 1, 4 or 6
C-EDGE CO-INFECTION: Conclusions

Conclusions: “This HCV treatment regimen seems to be effective and well tolerated for patients co-infected with HIV with or without cirrhosis. These data are consistent with previous trials of this regimen in the monoinfected population. This regimen continues to be studied in phase 3 trials.”

Source: Rockstroh JK, et al. Lancet HIV. 2015;2:e319-27.

Acknowledgment

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The content in this slide set does not represent the official views of the U.S. Department of Health and Human Services, Health Resources & Services Administration.

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