

Treatment Naïve

HIV Coinfection

Elbasvir + Grazoprevir +/- RBV: HCV GT1 +/- HIV Coinfection C-WORTHY Coinfection

Sulkowski M, et al. Lancet. 2015;385:1087-97.

Elbasvir + Grazoprevir +/- RBV in HCV GT1 +/- HIV Coinfection

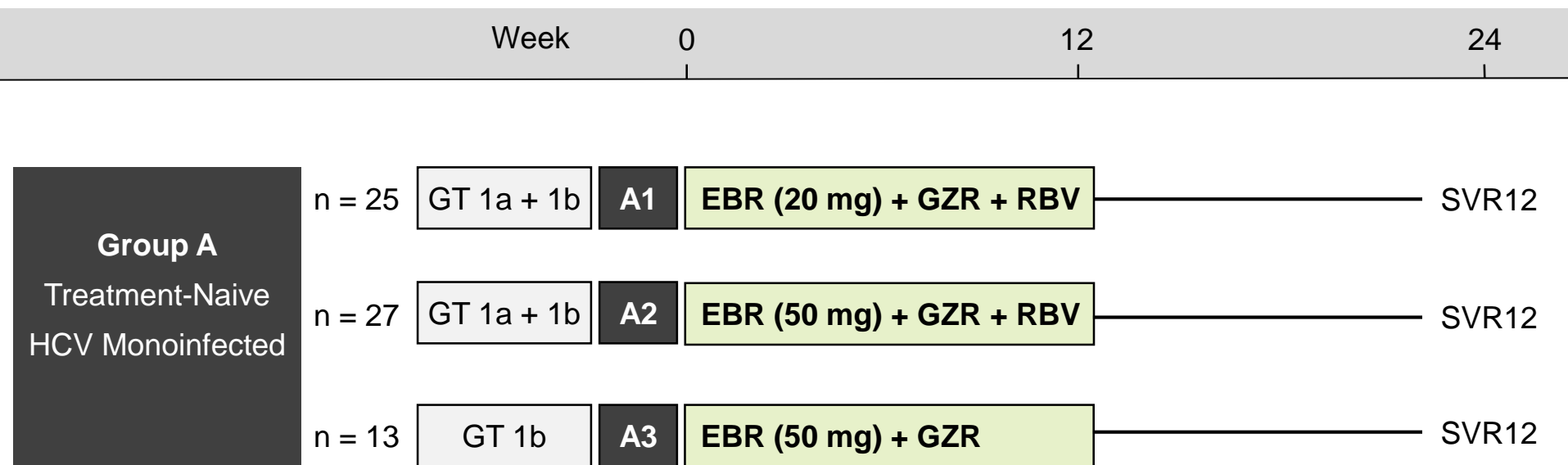
C-WORTHY Coinfection: Study Features

C-WORTHY (Protocol 035) Trial

- **Design:** Randomized, open-label phase 2 trial examining the safety and efficacy of a fixed-dose combination of elbasvir plus grazoprevir, with or without ribavirin, in treatment-naïve HCV-monoinfected (part A) or HCV-HIV coinfecting (part B) patients without cirrhosis
- **Entry Criteria**
 - Chronic HCV Genotype 1
 - 18 years or older
 - HCV RNA $\geq 10,000$ IU/mL
 - No prior treatment
 - No cirrhosis
 - Part B: well-controlled HIV infection (on antiretroviral therapy ≥ 8 weeks, HIV RNA undetectable $\times \geq 24$ weeks and CD4 count ≥ 300 cells/mm³)
- **Primary End-Point:** SVR12

Elbasvir + Grazoprevir +/- RBV in HCV GT1 +/- HIV Coinfection

C-WORTHY Coinfection: Study: Study Design Part A



Abbreviations: EBR = elbasvir; GZR = grazoprevir; RBV = ribavirin

Drug Dosing

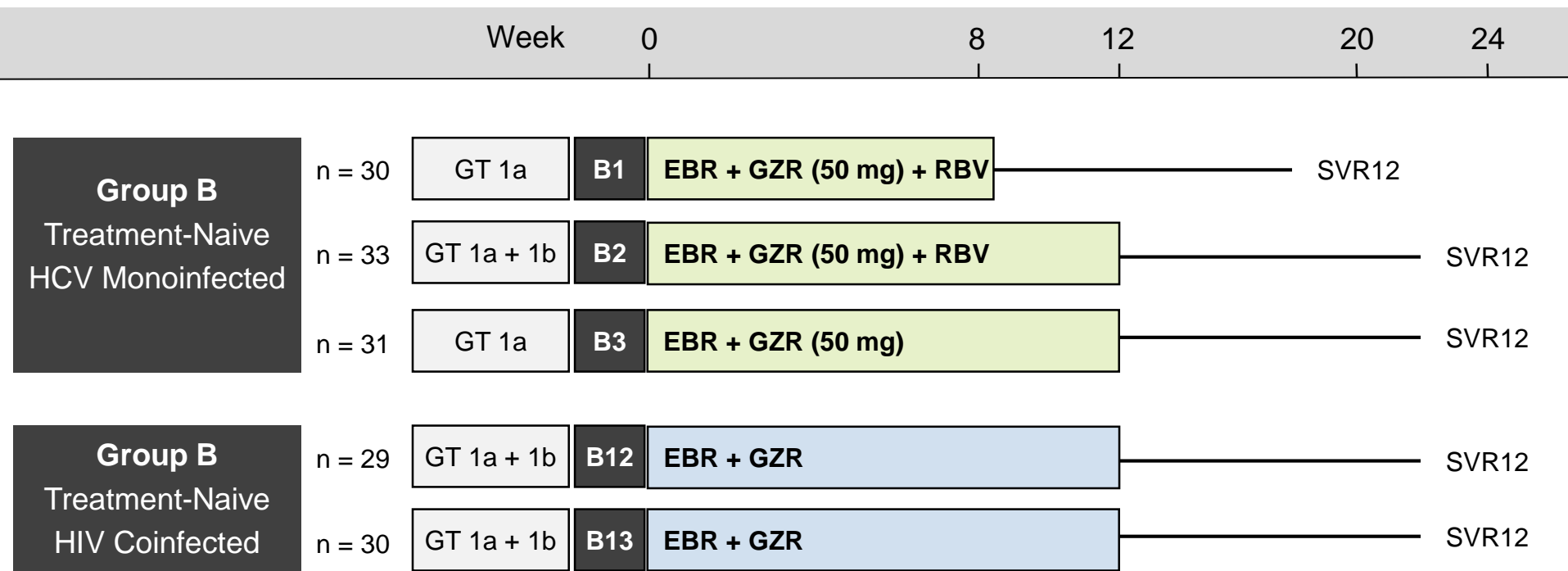
Elbasvir (20 mg or 50 mg) once daily

Grazoprevir (100 mg) once daily

Ribavirin (weight-based and divided bid): 800 to 1400 mg/day

Elbasvir+ Grazoprevir +/- RBV in HCV GT1 +/- HIV Coinfection

C-WORTHY Coinfection: Study: Study Design Part B



Abbreviations: EBR = elbasvir; GZR = grazoprevir; RBV = ribavirin

Drug Dosing

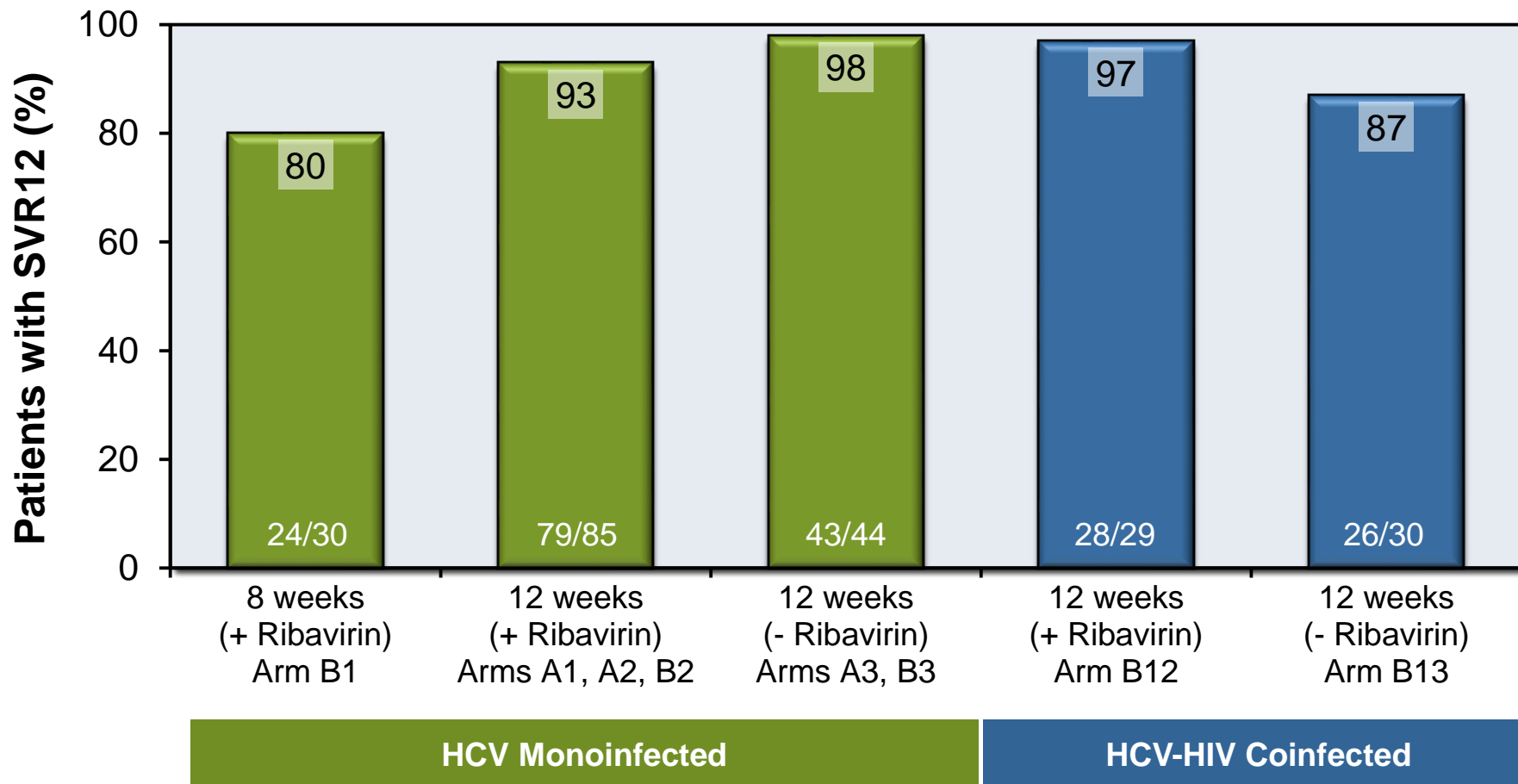
Elbasvir (50 mg) once daily

Grazoprevir (100 mg) once daily

Ribavirin (weight-based and divided bid): 800 to 1400 mg/day

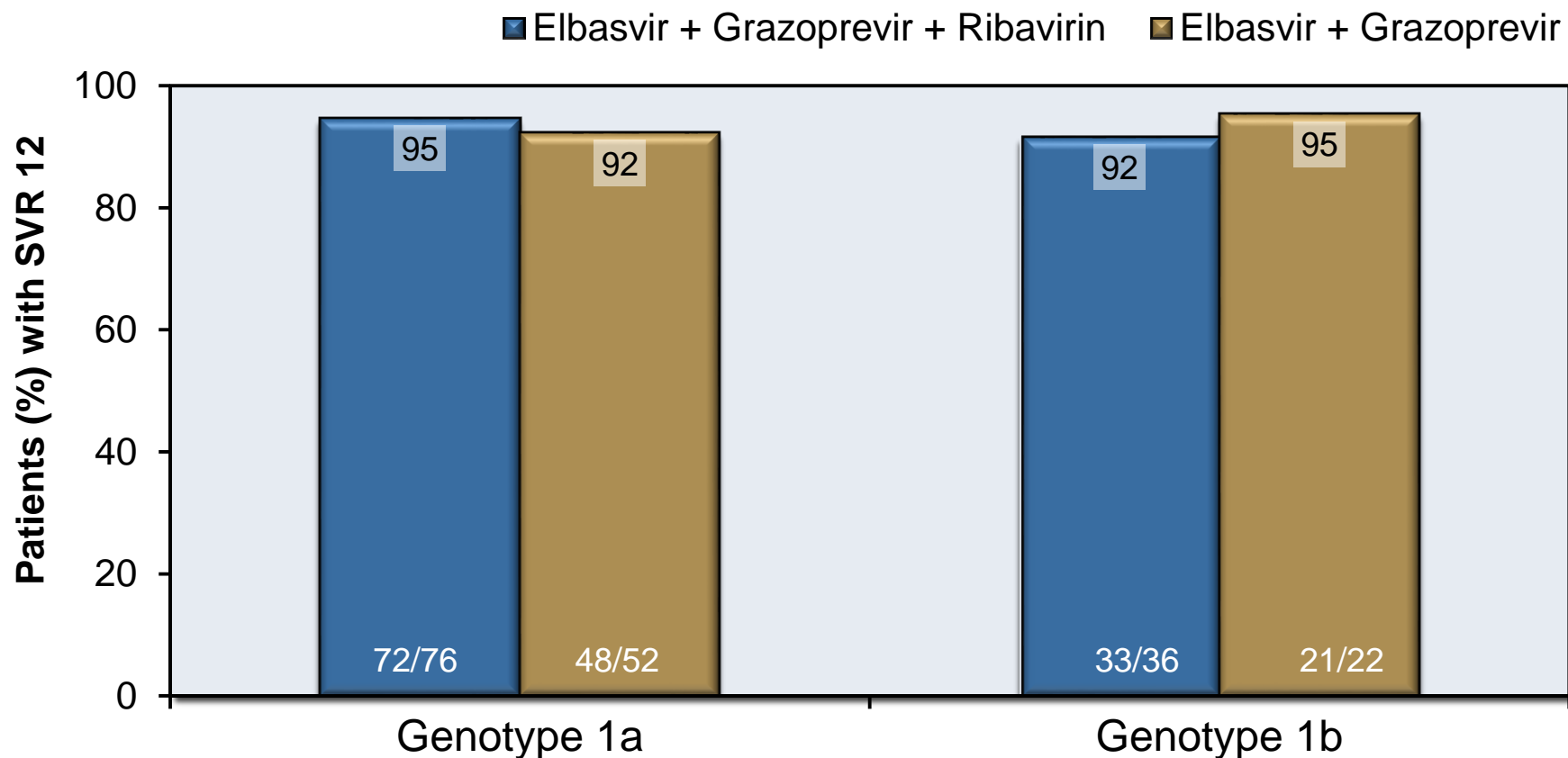
Elbasvir + Grazoprevir +/- RBV in HCV GT1 +/- HIV Coinfection C-WORTHY Coinfection: Results

C-WORTHY: SVR12 Results by Treatment and HIV Coinfection Status



Elbasvir + Grazoprevir +/- RBV in HCV GT1 +/- HIV Coinfection C-WORTHY Coinfection: Study: Results

C-WORTHY: SVR12 Rates by HCV GT1 Subtype and Use of Ribavirin



Elbasvir + Grazoprevir +/- RBV in HCV GT1 +/- HIV Coinfection C-WORTHY Coinfection: Study Features

Interpretation: “Once-daily grazoprevir plus elbasvir with or without ribavirin for 12 weeks in previously untreated HCV-mono-infected and HIV/HCV-co-infected patients without cirrhosis achieved SVR12 rates of 87-98%. These results support the ongoing phase 3 development of grazoprevir plus elbasvir.”