

Treatment Naïve

HIV Coinfection

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

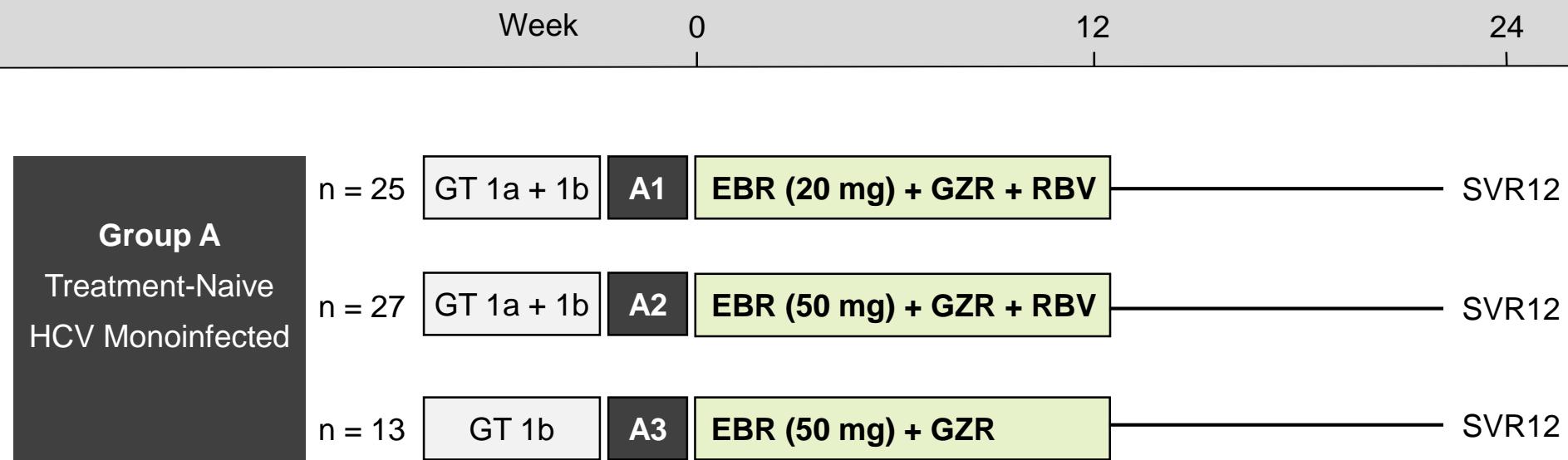
Source: Sulkowski M, et al. Lancet. 2015;385:1087-97.

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-grazoprevir, with or without ribavirin, in treatment-naïve HCV-monoinfected (part A) or HCV-HIV coinfecte
- **Entry Criteria**
 - Chronic HCV genotype 1
 - Age 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 \geq 8 weeks, HIV RNA undetectable x \geq 24 weeks and CD4 count \geq 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

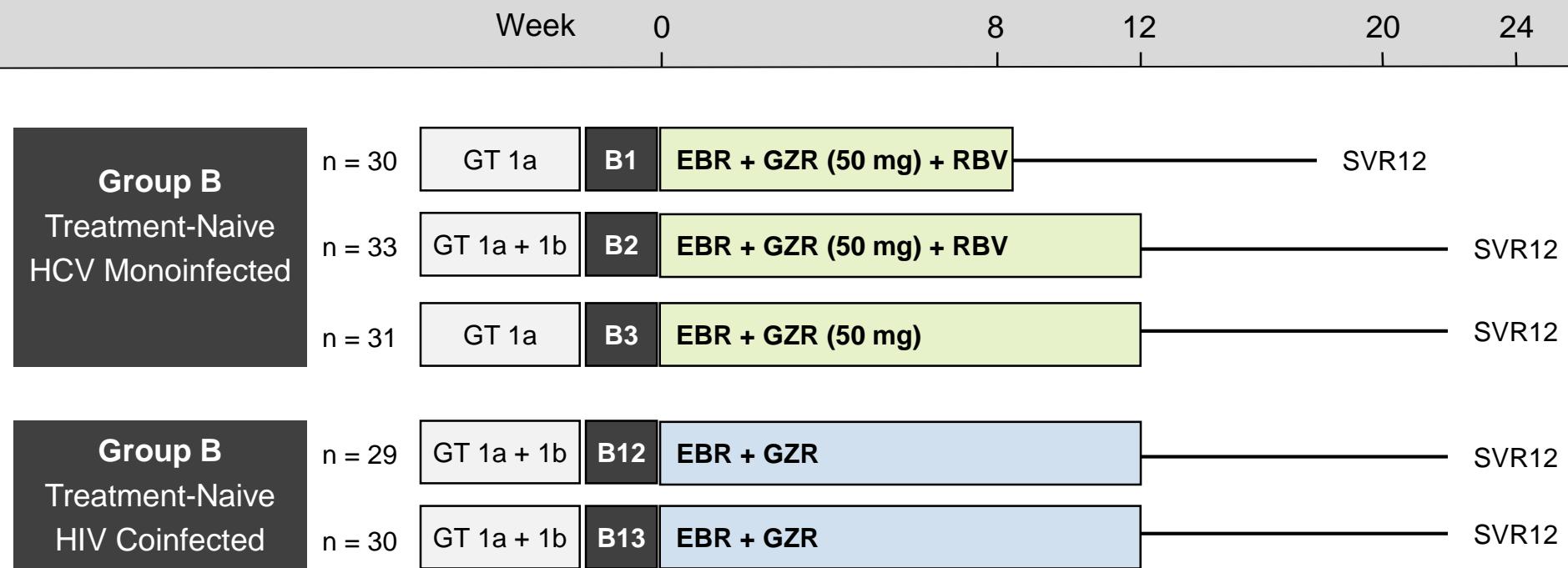
Drug Dosing

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



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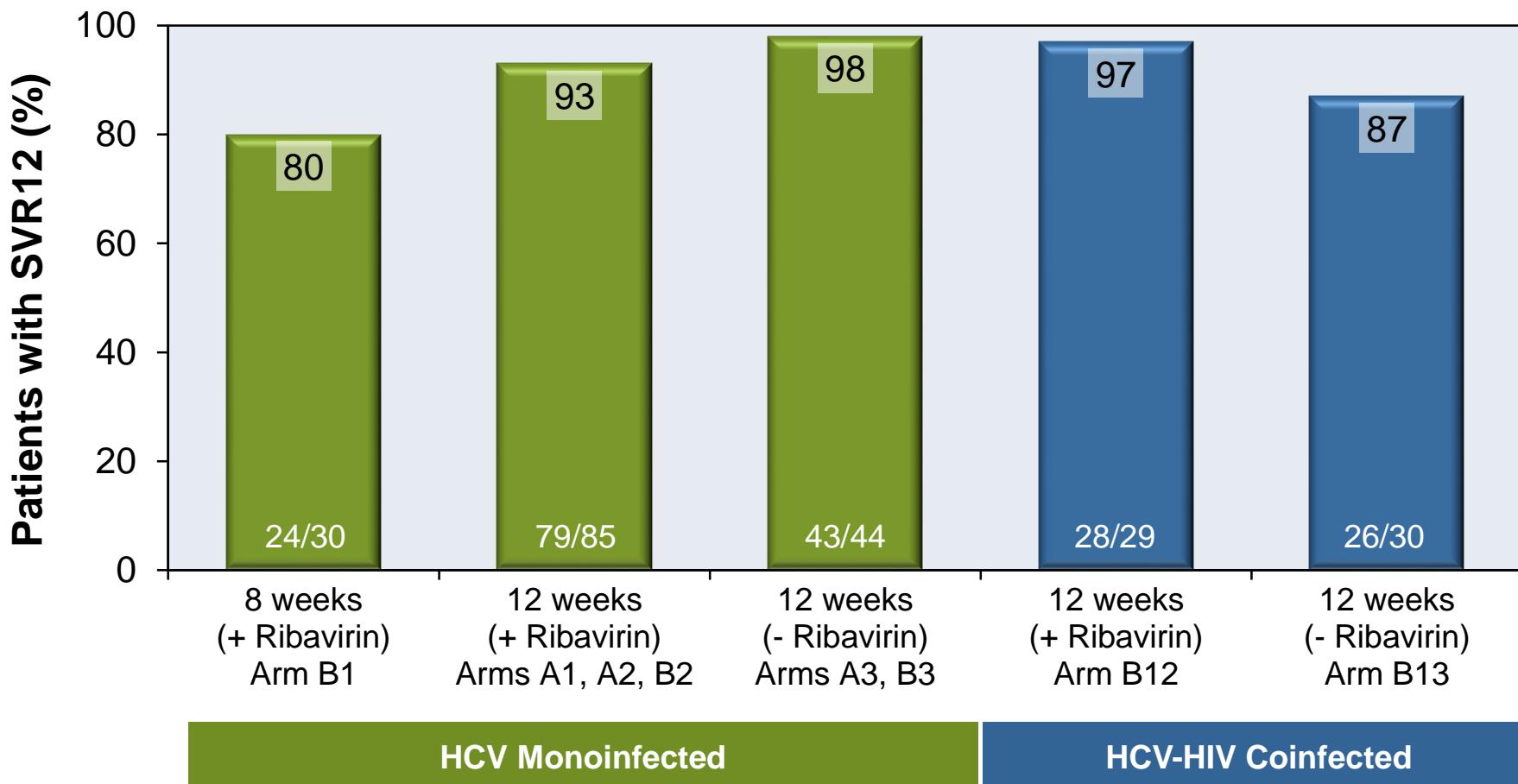
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Elbasvir + Grazoprevir +/- RBV in HCV GT1 +/- HIV Coinfection C-WORTHY Coinfection: Results

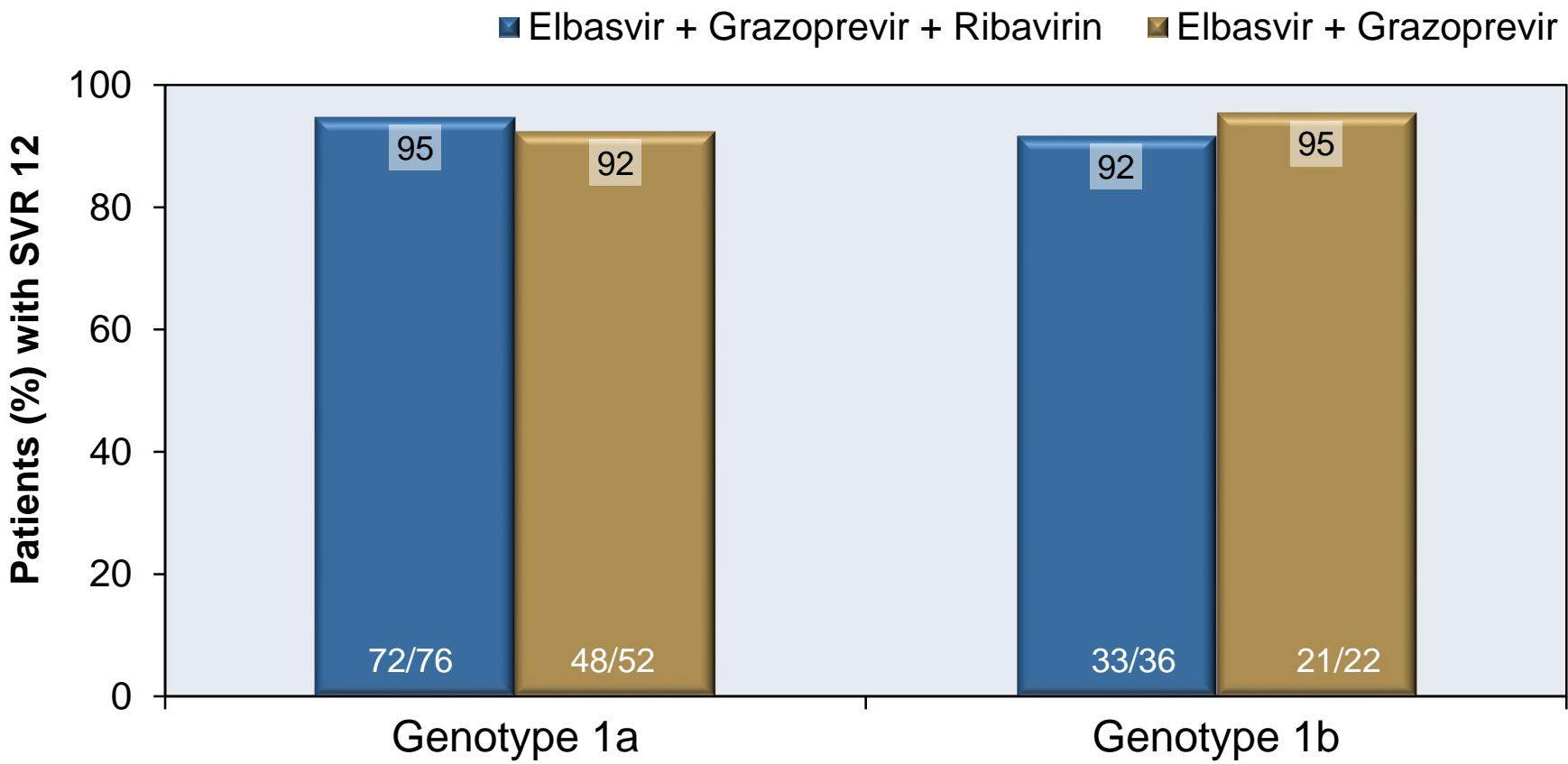
C-WORTHY: SVR12 Results by Treatment and HIV Coinfection Status



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

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



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

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.”