

Treatment Naïve

# Elbasvir-Grazoprevir + Sofosbuvir in Treatment-Naïve HCV Genotype 1 or 3 C-SWIFT

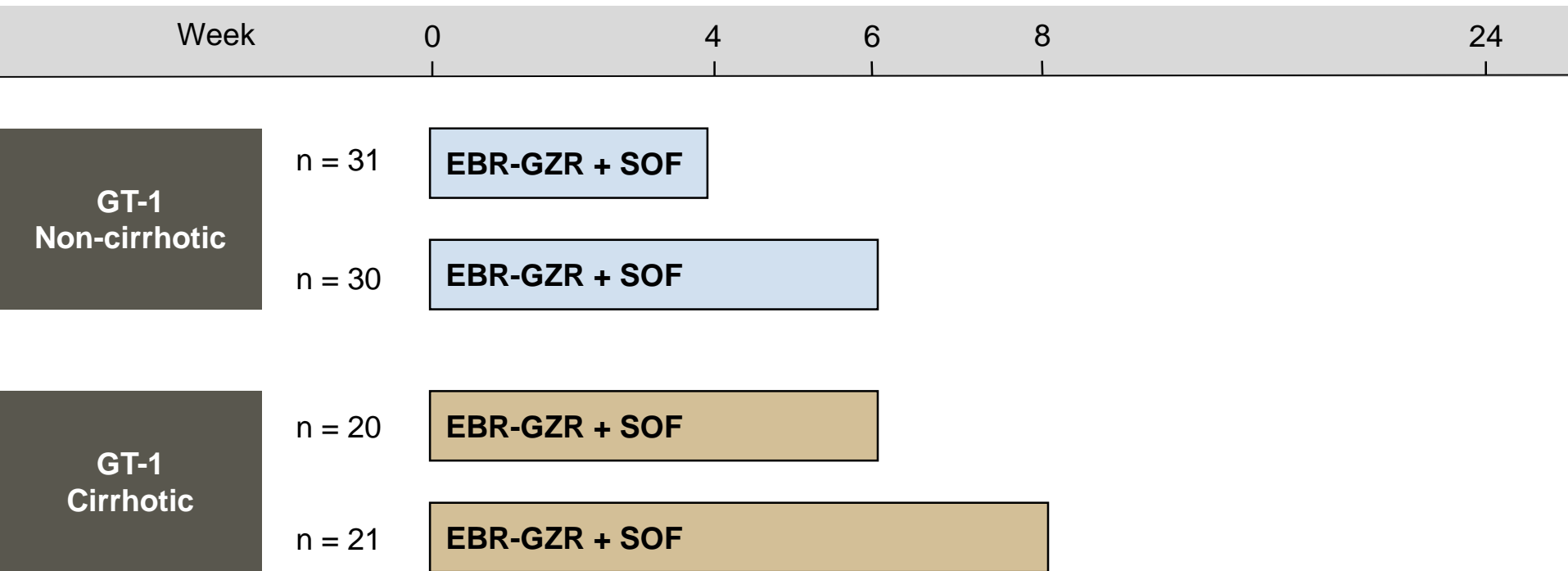
Source: Lawitz E, et al. Hepatology. 2017;65:439-50.

# Elbasvir-Grazoprevir + Sofosbuvir in Treatment-Naïve GT 1 or 3 C-SWIFT Study: Features

## C-SWIFT Trial

- **Design:** Open-label phase 2 trial to evaluate the efficacy and safety of short duration therapy with elbasvir-grazoprevir + sofosbuvir in treatment-naïve GT 1 or 3 infection, with or without cirrhosis
- **Entry Criteria**
  - Chronic HCV genotype 1 (n = 102) or genotype 3 (n = 41)
  - Age 18 years or older
  - No prior HCV treatment
  - HCV RNA  $\geq 10,000$  IU/mL
  - ALT and AST  $< 350$  IU/L
  - Cirrhosis allowed
- **Primary End-Point:** SVR12

# Elbasvir-Grazoprevir + Sofosbuvir in Treatment-Naïve GT 1 or 3 C-SWIFT Study: Study Design for GT 1



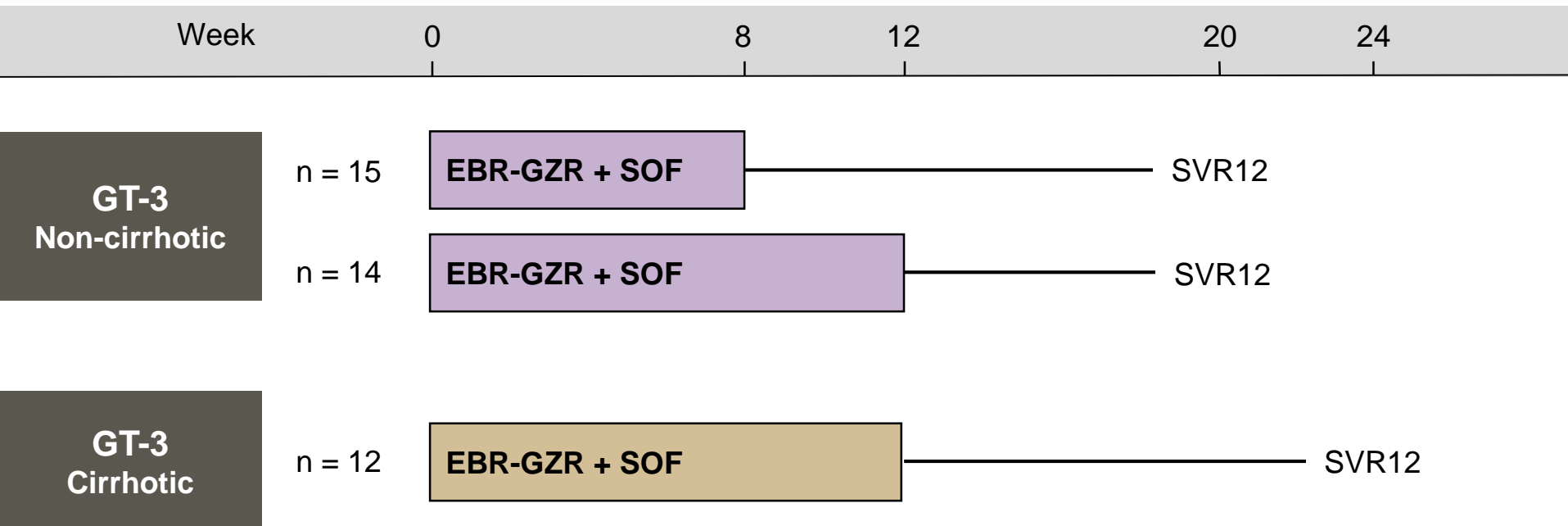
**Abbreviations:** EBR-GZR = elbasvir-grazoprevir; SOF = sofosbuvir

## Drug Dosing

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

Sofosbuvir: 400 mg once daily

# Elbasvir-Grazoprevir + Sofosbuvir in Treatment-Naïve GT 1 or 3 C-SWIFT Study: Study Design for GT 3



**Abbreviations:** EBR-GZR= grazoprevir-elbasvir; SOF = sofosbuvir

## Drug Dosing

Grazoprevir/elbasvir (100/50 mg): fixed dose combination; one pill once daily

Sofosbuvir 400 mg once daily

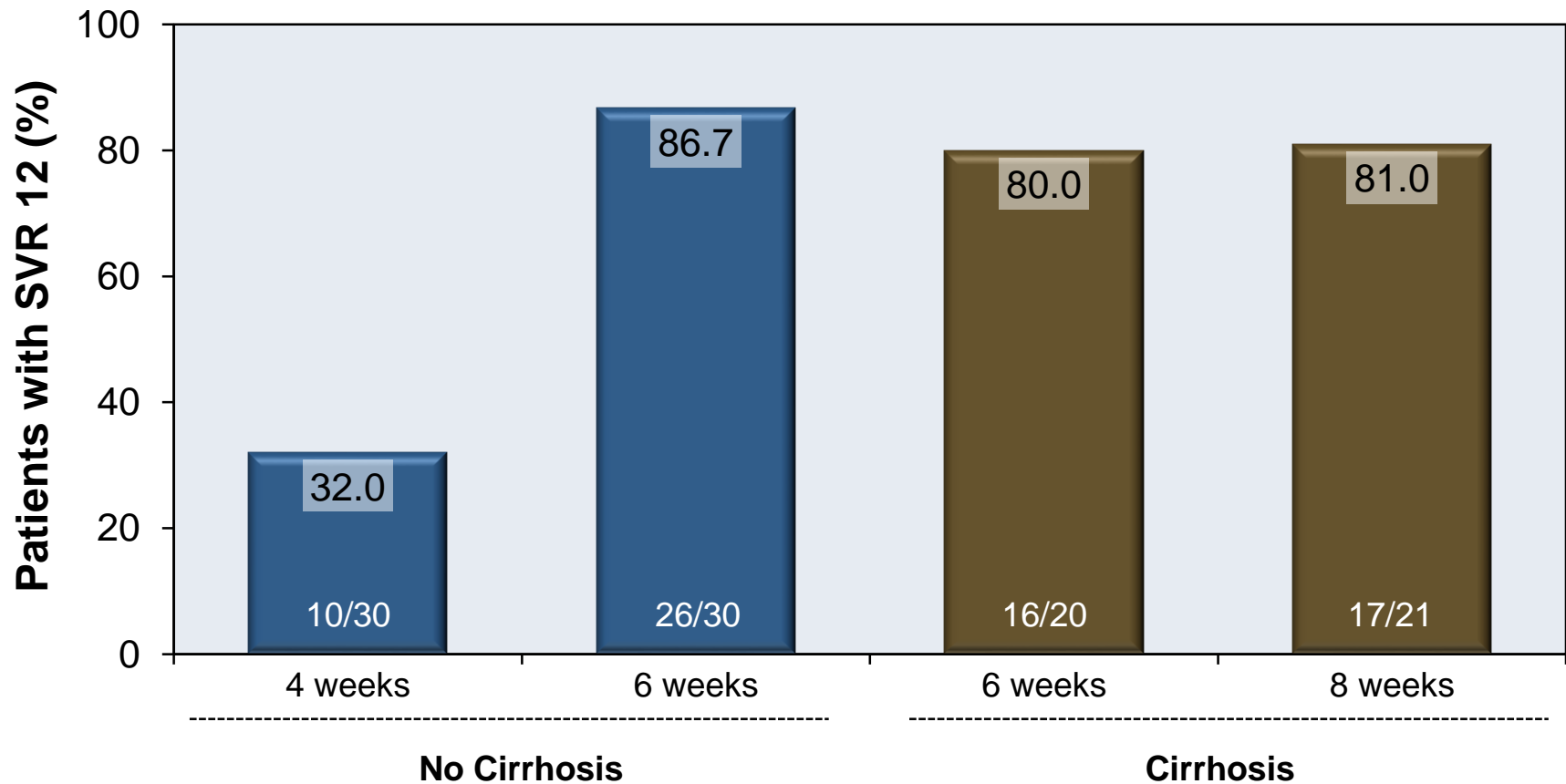
# Elbasvir-Grazoprevir + Sofosbuvir in Treatment-Naïve GT 1 or 3 C-SWIFT Study: Baseline Characteristics

Baseline Characteristic	Genotype 1				Genotype 3		
	No cirrhosis		Cirrhosis		No Cirrhosis		Cirrhosis
	4 weeks (n = 31)	6 weeks (n = 30)	6 weeks (n = 20)	8 weeks (n = 21)	8 weeks (n = 15)	12 weeks (n = 14)	12 weeks (n = 12)
Mean age, years	52	51	56	57	51	42	55
Male sex, %	65	63	65	62	73	57	83
Race, %							
White	97	93	100	95	100	100	100
Hispanic/Latino	29	47	65	48	40	57	50
HCV Genotype, %							
1a	84	87	80	76	--	--	--
1b	16	13	20	24	--	--	--
3	--	--	--	--	100	100	100
IL28B CC, %	36	27	30	24	40	21	50
Cirrhosis, %	0	0	100	100	0	0	100
HCV RNA, 10 <sup>6</sup> IU/mL (mean)	3.7	3.1	1.7	2.4	3.3	2.6	2.3

Source: Lawitz E, et al. *Hepatology*. 2017;65:439-50.

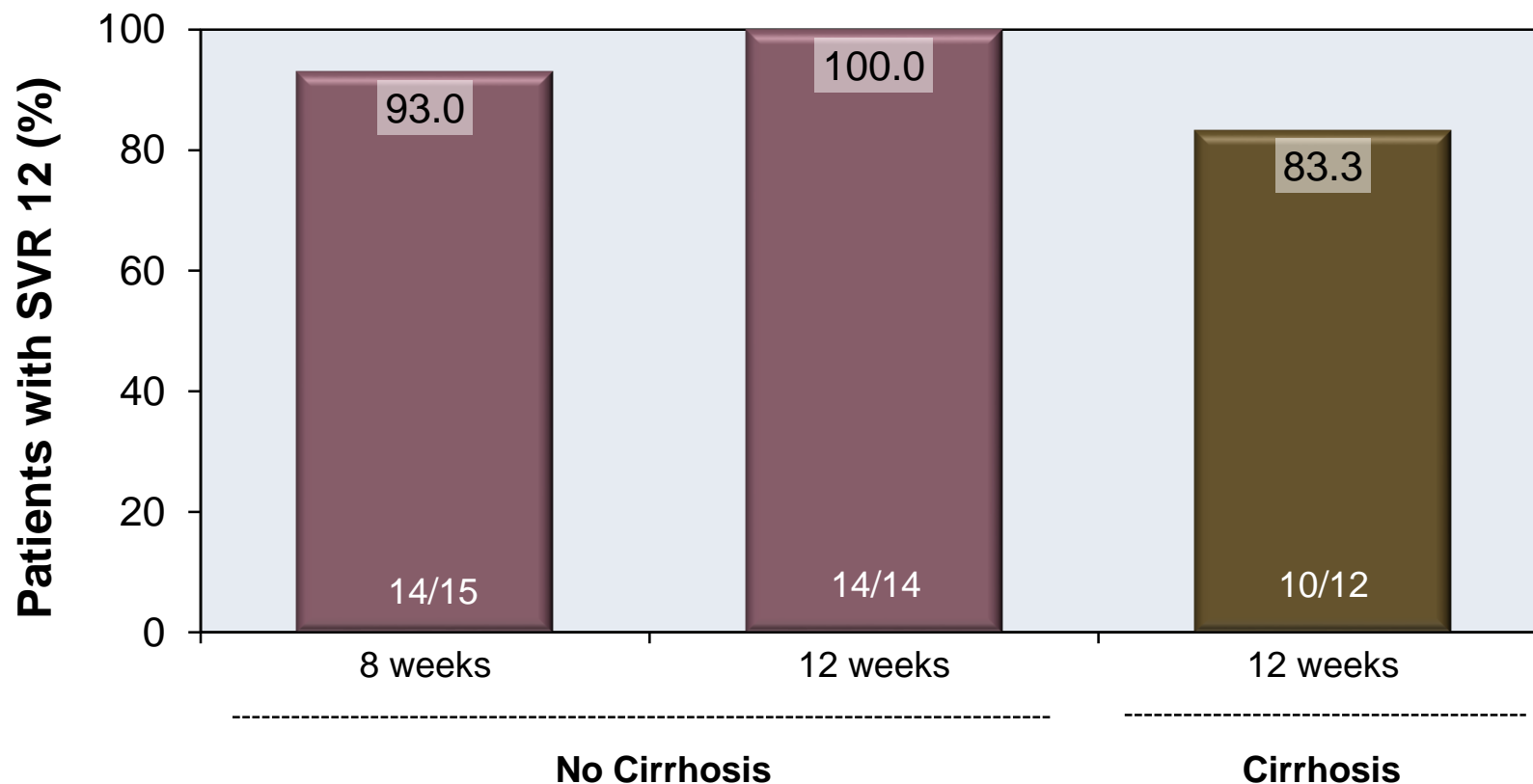
# Elbasvir-Grazoprevir + Sofosbuvir in Treatment-Naïve GT 1 or 3 C-SWIFT Study: Results for GT 1

C-SWIFT: SVR 12\* for GT 1 by Treatment Duration and Cirrhosis



# Elbasvir-Grazoprevir + Sofosbuvir in Treatment-Naïve GT 1 or 3 C-SWIFT Study: Results for GT 3

## C-SWIFT: SVR 12\* for GT 3 by Treatment Duration and Cirrhosis



# Elbasvir-Grazoprevir + Sofosbuvir in Treatment-Naïve GT 1 or 3 C-SWIFT Study: Conclusions

**Conclusions:** “Data from this study support the use of 8-week treatment regimens that maintain high efficacy, even for patients with HCV GT3 infection. Retreatment of patients who failed short-duration therapy was achieved through extended treatment duration and addition of ribavirin.