Elbasvir + Grazoprevir in GT 1 and Chronic Renal Disease

C-SURFER

Source: Roth D, et al. Lancet 2015;386:1537-45.

Elbasvir + Grazoprevir in HCV GT1 and Renal Disease
C-SURFER Study: Features

- **Design**: Randomized, phase 3, double-blind trial examining the safety and efficacy of elbasvir plus grazoprevir for 12 weeks in treatment-naïve or treatment-experienced patients genotype 1 chronic HCV and stage 4 or 5 chronic renal disease, including patients on hemodialysis.
- **Setting**: 68 international sites
- **Entry Criteria**
  - Chronic HCV genotype 1
  - Chronic kidney disease (Stage 4 or 5) +/- hemodialysis
  - Age 18 years or older
  - Treatment naïve or treatment-experienced
  - Cirrhosis allowed
- **Primary End-Point**: SVR12

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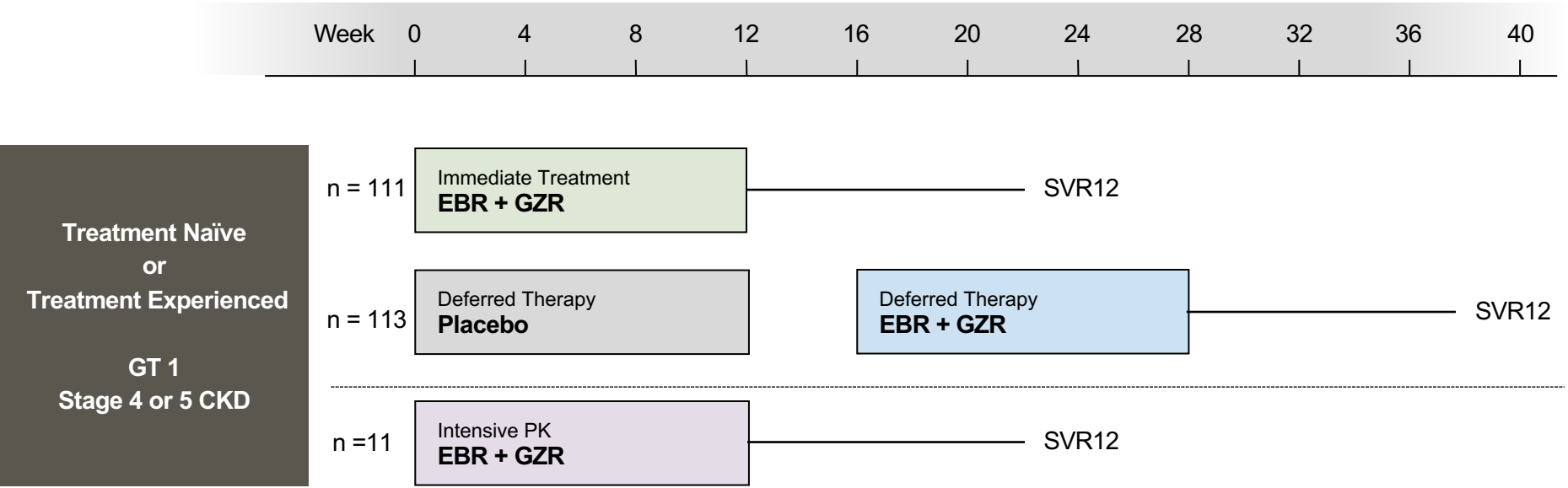
C-SURFER Study: Study Design



Drug Dosing
Elbasvir 50 mg once daily and Grazoprevir 100 mg once daily; given as separate medications in Immediate treatment and Intensive PK arms; given as fixed dose combination in Deferred arm

Source: Roth D, et al. Lancet 2015;386:1537-45.

Acknowledgments

Hepatitis C Online is funded by a cooperative agreement from the Centers for Disease Control and Prevention (CDC-RFA- PS21-2105). This project is led by the University of Washington Infectious Diseases Education and Assessment (IDEA) Program.

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Elbasvir + Grazoprevir in HCV GT1 and Renal Disease
C-SURFER Study: Participants

Baseline Characteristic	EBR + GZR *Immediate* (n = 111)	EBR + GZR *Deferred* (n = 113)	EBR + GZR *PK* (n = 11)	Total (n = 235)
Mean age, years (SD)	56.5 (9.1)	55.2 (10.1)	58.2 (6.8)	56 (9.5)
Male sex, %	73	71	100	73
Race, %				
White	50	43	54	47
Black	45	47	45	46
Asian	5	8	0	6
HCV Genotype, %				
1a	48	52	91	52
1b	52	47	9	48
1 other	0	1	0	0
Cirrhosis, %	6	6	0	6
Treatment-naïve, %	82	78	91	80
Diabetes, %	34	32	55	34
Kidney disease severity				
Stage 4, %	16	20	36	19
Stage 5, %	84	80	64	81
On dialysis, %	78	77	55	76

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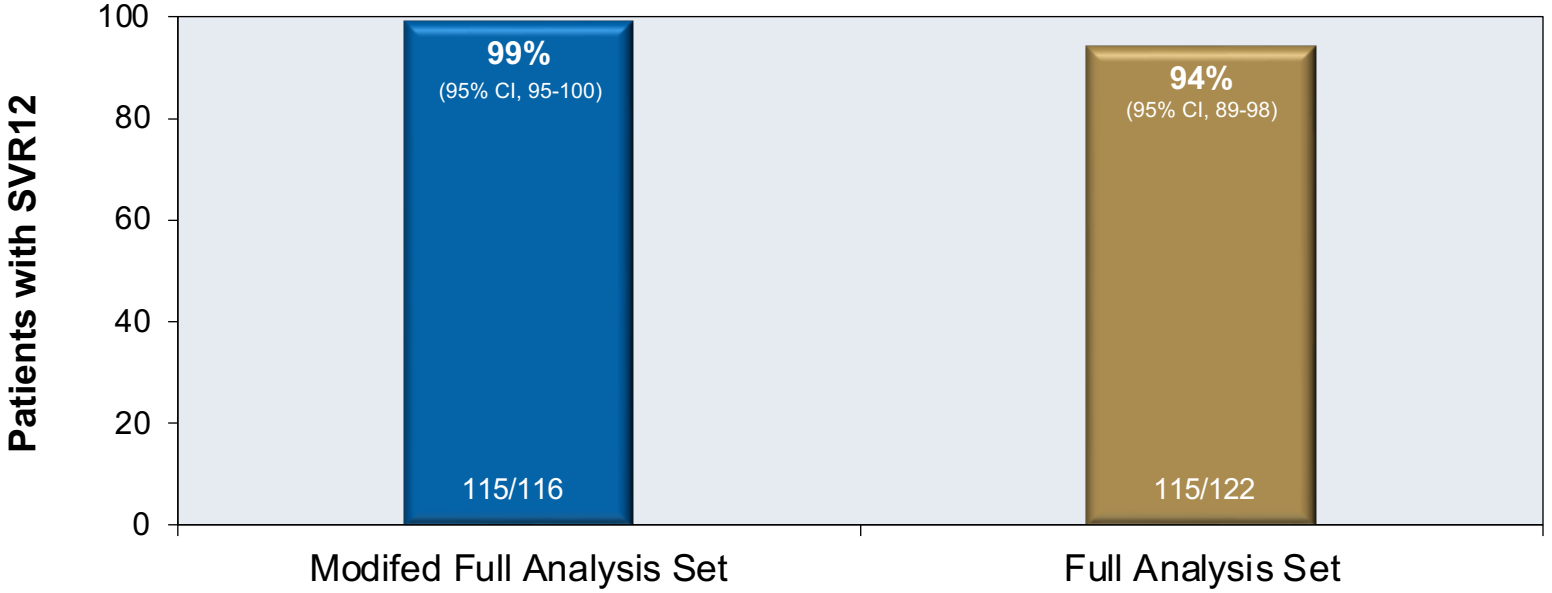
C-SURFER Study: Results

C-SURFER: Elbasvir + Grazoprevir SVR12 Results



Modified analysis excluded patients who did not receive ≥1 dose of drug or who died or discontinued early for reasons unrelated to HCV treatment.

Source: Roth D, et al. Lancet 2015;386:1537-45.

Elbasvir + Grazoprevir in HCV GT1 and Renal Disease
C-SURFER Study: Safety

Adverse Event (AE), n (%)	Elbasvir + Grazoprevir	
	Immediate (n = 111)	**Deferred** (Placebo) (n = 113)
Discontinuation due to AE	0	5 (4.4)
Serious AEs	16 (14.4)	19 (16.8)
Deaths	1 (0.8)	3 (2.7)
Any AE in ≥10% of patients	84 (75.7)	95 (84.1)
Headache	19 (17.1)	19 (16.8)
Nausea	17 (15.3)	18 (15.9)
Fatigue	11 (9.9)	17 (15.9)
Insomnia	7 (6.3)	12 (10.6)
Dizziness	6 (5.4)	18 (15.9)
Diarrhea	6 (5.4)	15 (13.3)
Laboratory AEs		
Hemoglobin <8.5 g/dl	5 (4.5)	5 (4.4)
ALT 1.1-2.5 x baseline	2 (1.8)	36 (31.9)
Creatinine[§] >2.5 x baseline	1 (1.2)	0

[§]Among patients not on dialysis at baseline.

Source: Roth D, et al. Lancet 2015;386:1537-45.

Elbasvir + Grazoprevir in HCV GT1 and Renal Disease
C-SURFER Study: Conclusions

Conclusions: “Once-daily grazoprevir and elbasvir for 12 weeks had a low rate of adverse events and was effective in patients infected with HCV genotype 1 and stage 4-5 chronic kidney disease.”

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