

# DRUG USE AND REINFECTION DURING AND FOLLOWING HEPATITIS C VIRUS TREATMENT WITH ELBASVIR/GRAZOPREVR AMONG PATIENTS RECEIVING OPIATE AGONIST THERAPY: C-EDGE CO-STAR STUDY

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## CO-START: PART A AND PART B STUDY DESIGN

### Part A Study Design

- Phase 3, randomized trial of EBR/GZR for 12 weeks (n=301)
- Participants: GT1, 4, 6 on OAT for  $\geq 3$  months
- Urine drug screen performed at each visit
- **SVR12: ITT 91%, mITT 96%** (reinfection not counted as failure and LTFU cases excluded)
- 6 cases of HCV reinfection (5 EOT to SVR12, 1 SVR12 to SVR24)

### Part B Study Design

- 3 year follow-up open to all participants from Part A
- Assessments every 6 months
  - HCV RNA
    - Comparison of viral sequences at baseline and virologic recurrence to determine reinfection
  - Urine drug screen
  - Participant-reported behaviors
    - Behavioral questionnaire: self-reported drug use



## BASELINE CHARACTERISTICS: PART B ENROLLED AND NOT ENROLLED

	Participants enrolled in Part B (n = 199)	Participants not enrolled in Part B (n = 97)		Participants enrolled in Part B (n = 199)	Participants not enrolled in Part B (n = 97)
Male, n (%)	151 (76)	76 (78)	Positive urine drug screen at enrollment of Part A, n (%)	117 (59)	66 (68)
<b>Age, years, median (range)</b>	<b>48.6 (24-66)</b>	<b>44.1 (23-64)</b>	<b>Amphetamines</b>	<b>13 (7)</b>	<b>4 (4)</b>
Race, n (%)			<b>Cocaine</b>	<b>19 (10)</b>	<b>12 (12)</b>
White	158 (79)	80 (82)	<b>Opiates</b>	<b>44 (22)</b>	<b>23 (24)</b>
African American	31 (16)	6 (6)	Benzodiazepines	47 (24)	36 (37)
Asian/other	10 (5)	11 (11)	Cannabinoids	46 (23)	42 (43)
HCV/HIV co-infected, n (%)	16 (8)	5 (5)			
OAT at day 1 active treatment, n (%)					
Methadone	159 (80)	75 (77)			
Buprenorphine	39 (20)	21 (22)			
Genotype, n (%)					
1a	144 (72)	81 (84)			
1b	39 (20)	5 (5)			
4	7 (4)	2 (2)			
6	2 (1)	5 (5)			
Mixed	7 (4)	4 (4)			
Presence of cirrhosis (F4), n (%)	44 (22)	18 (19)			



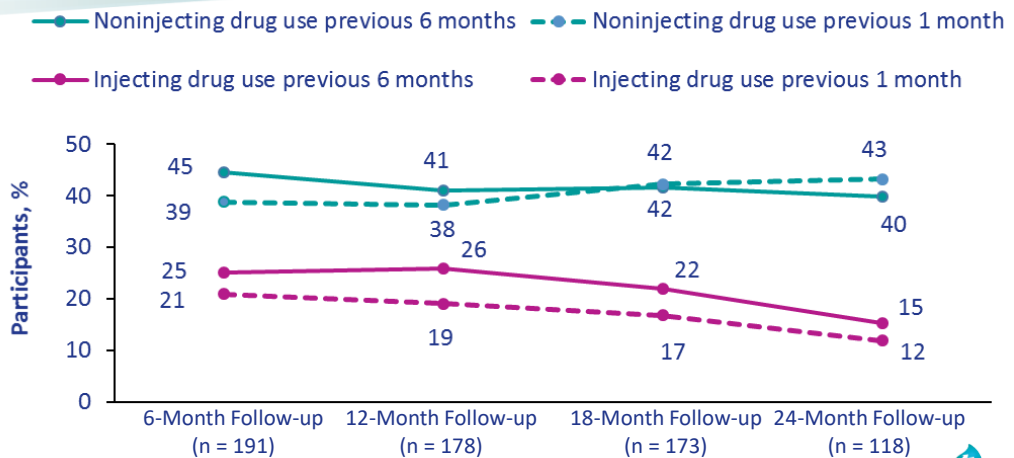
## PART B: ONGOING RISK BEHAVIOR—URINE DRUG SCREEN

	Participants With Urine Drug Screen Results						
	Part A Day 1 (n = 199)	Part B Day 1 (n = 192)	6-Month Follow-up (n = 190)	12-Month Follow-up (n = 177)	18-Month Follow-up (n = 172)	24-Month Follow-up (n = 152)	30-Month Follow-up (n=142)
Any positive urine drug screen <sup>a</sup>	59%	60%	59%	62%	59%	59%	53%
<b>Amphetamines</b>	<b>7%</b>	<b>8%</b>	<b>8%</b>	<b>5%</b>	<b>6%</b>	<b>3%</b>	<b>4%</b>
<b>Cocaine</b>	<b>10%</b>	<b>12%</b>	<b>11%</b>	<b>14%</b>	<b>13%</b>	<b>16%</b>	<b>13%</b>
<b>Opioids</b>	<b>22%</b>	<b>27%</b>	<b>21%</b>	<b>24%</b>	<b>27%</b>	<b>25%</b>	<b>23%</b>
Benzodiazepines	24%	24%	23%	21%	23%	17%	16%
Cannabinoids	23%	28%	28%	29%	29%	29%	28%

<sup>a</sup>Excludes methadone and buprenorphine.



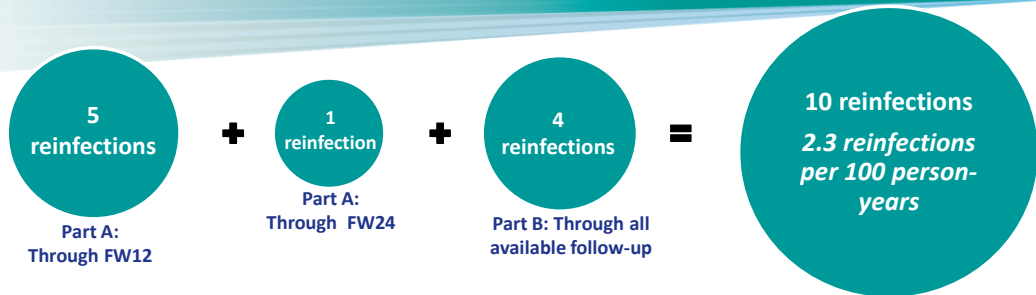
## PART B: ONGOING RISK BEHAVIOR—REPORTED DRUG USE<sup>a</sup>



<sup>a</sup>Participants may have reported both injection and noninjection drug use.



## INCIDENCE OF REINFECTION



All Refections: From End of Treatment Through 36 Months of Follow-up

• 10 refections	• 426 person-years	• 2.3 refections per 100 person-years (95% CI: 1.1, 4.3)
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CI, confidence interval; FW, follow-up week.



## CONCLUSIONS

- **Drug use patterns remained stable during the 36 months of follow-up**
  - UDS results comparable over time with respect to each drug class
  - Rate of injection drug use in previous 6 months: 16-26%
- **10 participants with refection during the follow-up period**
- **Refection rate of 2.3/100 person-years**
  - Higher rate of refection in early follow-up period may be due to more frequent follow-up

