

# DRUG USE AND REINFECTION DURING AND FOLLOWING HCV TREATMENT WITH ELBASVIR/GRAZOPREVRIR AMONG PATIENTS RECEIVING OPIOID AGONIST THERAPY: FINAL RESULTS FROM THE CO-STAR STUDY

*Jason Grebely<sup>1</sup>, Brian Conway<sup>2</sup>, Alain H. Litwin<sup>3</sup>, Olav Dalgard<sup>4</sup>, Oren Shibolet<sup>5</sup>, Ronald Nahass<sup>6</sup>, Frederick Altice<sup>7</sup>, Edward J. Gane<sup>8</sup>, Anne Luetkemeyer<sup>9</sup>, Cheng-Yuan Peng<sup>10</sup>, David Iser<sup>11</sup>, Isaias Noel Gendrano<sup>12</sup>, Michelle M. Kelly<sup>12</sup>, Peggy Hwang<sup>12</sup>, Eliav Barr<sup>12</sup>, Michael N. Robertson<sup>12</sup>, Heather Platt<sup>12</sup>, Gregory J. Dore<sup>1</sup>*

<sup>1</sup>The Kirby Institute, UNSW Sydney, Sydney, NSW, Australia; <sup>2</sup>Vancouver Infectious Diseases Centre, Vancouver, <sup>3</sup>Albert Einstein College of Medicine/Montefiore Medical Center, Bronx, NY, USA; <sup>4</sup>Institute of Clinical Medicine, Akershus University, Oslo, Norway; <sup>5</sup>Liver Unit, Department of Gastroenterology, Tel Aviv Medical Center and Tel Aviv University, Tel Aviv, Israel; BC, Canada; <sup>6</sup>ID Care, Hillsborough, NJ, USA; <sup>7</sup>Yale University, New Haven, CT, USA; <sup>8</sup>Auckland City Hospital, Auckland, New Zealand; <sup>9</sup>University of California, San Francisco, San Francisco, CA, USA; <sup>10</sup>China Medical University Hospital, Taichung, Taiwan; <sup>11</sup>St. Vincent's Hospital, Melbourne, VIC, Australia; <sup>12</sup>Merck & Co., Inc., Kenilworth, NJ, USA

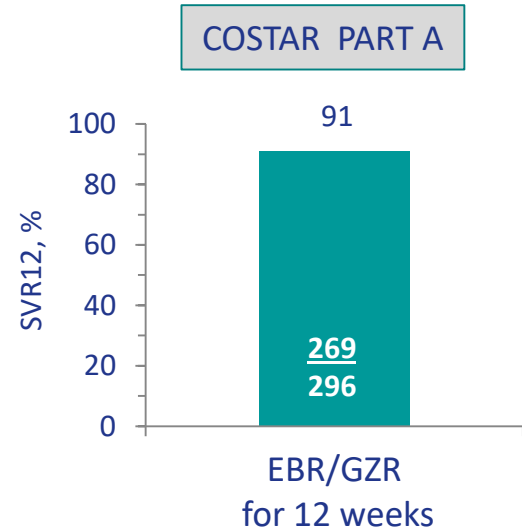
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# BACKGROUND / AIM

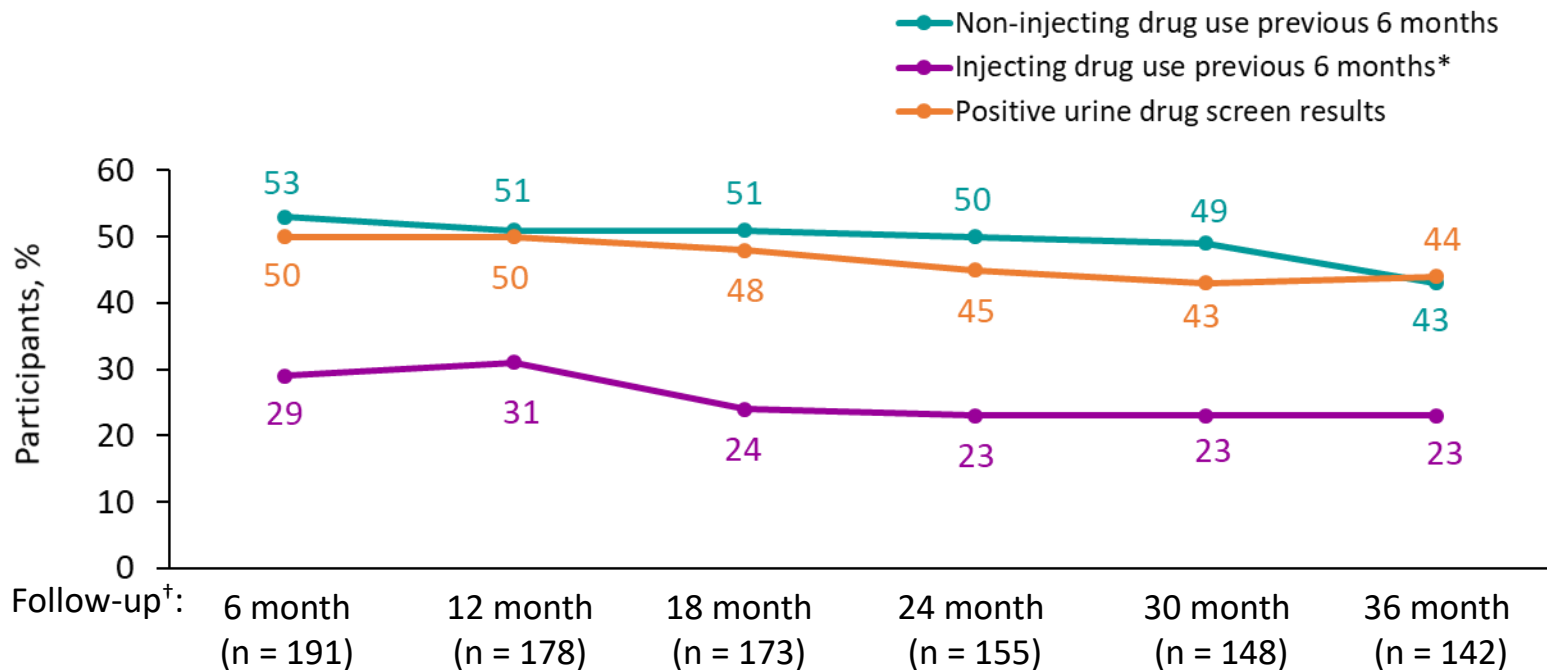
- CO-STAR: evaluation of elbasvir/grazoprevir 12 weeks in PWID receiving OAT<sup>1</sup>
- CO-STAR Part A
  - Phase 3, randomized, placebo-controlled
  - HCV GT1, 4, or 6 infection on OAT for  $\geq 3$  months
  - 45% with positive Urinary Drug Screen at baseline\*
  - 97% of participants with  $>95\%$  adherence
- CO-STAR Part B
  - A 3-year long term follow-up study to evaluate HCV reinfection and injecting risk behaviours in people from CO-STAR Part A



\* Excludes methadone, buprenorphine and cannabinoids

1. Dore, GJ et al Ann Intern Med. 2016;165:625-634

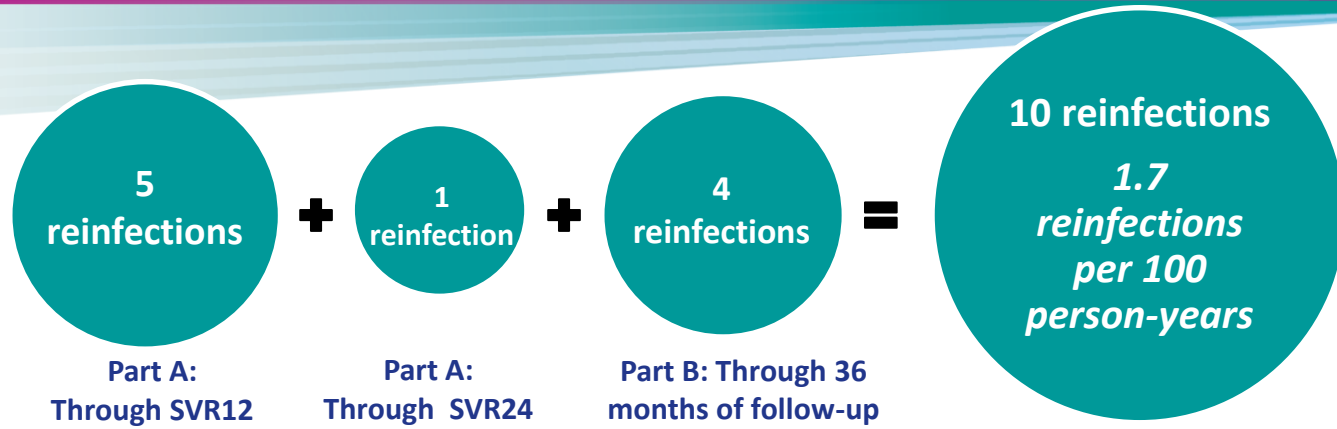
# RISK BEHAVIOUR: REPORTED DRUG USE AND URINE DRUG SCREEN



\*Includes heroin, cocaine, amphetamine, other opiate or benzodiazepine injection drug use at any time in the previous 6 months

<sup>†</sup>UDS data are based on n values of 190, 177, 172, 152, 143, and 137 for the 6, 12, 18, 24, 30 and 36 month follow-up visits, respectively

# INCIDENCE OF REINFECTION



	Number of reinfections	Person years follow-up*	Reinfection rate per 100-person years (95% CI)
<b>All persons (n = 296)</b>	<b>10</b>	<b>604</b>	<b>1.7 (0.8, 3.0)</b>
Part B (n = 199)			
Persons who reported injecting drug use (n = 95 <sup>†</sup> )	6 <sup>†</sup>	275	2.2 (0.8, 4.8)
Persons who did not report injecting drug use (n = 96 <sup>‡</sup> )	1	287	0.3 (<0.1, 1.9)

\*From end of treatment through 36 months of follow-up

<sup>†</sup>Of these 6 reinfections, 3 occurred during Part A and 3 occurred during Part B

<sup>‡</sup>Includes 191 patients who provided a response regarding drug use in at least 1 AQB questionnaire

# CONCLUSIONS

- Drug use patterns reasonably stable through 36 months follow-up
  - 23-31% of people reported injection drug use in the previous 6 months
- Overall reinfection rate of 1.7/100 person-years (py)
  - Reinfection rate 2.2/100 py among those with reported injection drug use
  - Higher number of reinfection cases in early follow-up period: more frequent follow-up?
- Of the 10 participants with reinfection
  - 8 had persistent reinfection
    - 4 were re-treated outside of the clinical trial
  - 2 had spontaneous clearance
    - 1 had a second reinfection: first reinfection at FW8, after spontaneous clearance, 2nd reinfection detected at 30M follow-up visit
- HCV reinfection monitoring and retreatment a key component of HCV elimination