SAFETY AND EFFICACY OF GLECAPREVIR/PIBRENTASVIR FOR 8 WEEKS FOR PEOPLE WITH ACUTE HEPATITIS C VIRUS INFECTION WHO USE DRUGS: A SUB-ANALYSIS OF A MULTICENTER, PROSPECTIVE PHASE 3 STUDY

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Background:
Most new cases of hepatitis C virus (HCV) infection occur among people who use drugs (PWUD) and in men who have sex with men. Identification of acute HCV infection presents an opportunity to offer early treatment, promote engagement in care, and reduce onward transmission. Identifying acute HCV infection and confirming efficacy of treatment among PWUD is an unmet need. Here, we report the efficacy and safety of glecaprevir/pibrentasvir (G/P) in PWUD with acute HCV infection, with and without HIV co-infection, from a phase 3 clinical trial.

Methods:
An 8-week G/P regimen was evaluated in adults with acute HCV infection. Illicit drug use was self-reported. Efficacy (sustained virologic response at post-treatment Week 12 [SVR12]) in the intention-to-treat (ITT, participants who received ≥1 G/P dose) and modified ITT (mITT, excluding those who failed SVR12 for non-virologic reasons) sets and safety were assessed.

Results:
Among 286 participants enrolled and treated, 137 (47.9%) reported current (n=49) or recent (n=88) illicit drug use (Table).

For current/recent PWUD in the ITT set, the SVR12 rate was 93.4% (128/137; mITT: 100% [128/128]); SVR12 rates were 95.7% (67/70) and 87.8% (36/41) in subgroups with HIV co-infection and current/recent injection drug use, respectively. For former/non-PWUD in the ITT set, the SVR12 rate was 98.7% (147/149; mITT: 100% [147/147]).

Serious adverse events occurred in 3.6% (5/137) of current/recent PWUD and 3.4% (5/149) of former/non-PWUD; none were deemed related to G/P and none led to treatment discontinuation. All participants with baseline grade ≥2 ALT improved by the final treatment visit.

Conclusion:
G/P demonstrated high efficacy and was well-tolerated in PWUD with acute HCV infection. Systematic campaigns to identify those with acute HCV infection with an offer of immediate antiviral treatment should be undertaken, providing benefit to both the individual and to the PWUD population as a whole.

Table. Baseline characteristics and demographics (ITT set).

Characteristic	Current/ recent PWUD (n=137)	Former/ non-PWUD (n=149)	Overall (N=286)
Median age (min, max), yr	40 (22, 67)	45 (20, 78)	43 (20, 78)

Male, n (%)	129 (94.2)	126 (84.6)	255 (89.2)
Race, n (%)			
White	124 (90.5)	122 (81.9)	246 (86.0)
Black/African American	5 (3.6)	25 (16.8)	30 (10.5)
Asian	5 (3.6)	2 (1.3)	7 (2.4)
Multiple	3 (2.2)	0	3 (1.0)
Hispanic/Latino ethnicity, n (%)	39 (28.5)	37 (24.8)	76 (26.6)
Risk behaviors, n (%)*			
Multiple unprotected sexual partners	90 (65.7)	82 (55.0)	172 (60.1)
Unprotected sexual activity with other males	98 (71.5)	92 (61.7)	190 (66.4)
Shared drug injection equipment	39 (28.5)	15 (10.1)	54 (18.9)
Shared personal items possibly contaminated with blood	14 (10.2)	6 (4.0)	20 (7.0)
HCV RNA ≥1 million IU/mL, n (%)	48 (35.0)	40 (26.8)	88 (30.8)
Prior HCV infection, n (%)	28 (20.4)	24 (16.1)	52 (18.2)
HCV genotype, n (%)†			
1	80 (65.6)	85 (63.0)	165 (64.2)
2	2 (1.6)	9 (6.7)	11 (4.3)
3	13 (10.7)	20 (14.8)	33 (12.8)
4	27 (22.1)	21 (15.6)	48 (18.7)
Missing	15	14	29
HIV co-infection, n (%)	70 (51.1)	72 (48.3)	142 (49.7)
Injection drug use			
Current/recent	41 (29.9)	0	41 (14.3)
Former/non	96 (70.1)	149 (100)	245 (85.7)

ITT, intention-to-treat; PWUD, people who use drugs.
* Participants may be counted under multiple categories; therefore, the sum of the counts may be greater than the overall number of participants; † HCV genotype was from phylogenetic analysis, or from the central lab if a phylogenetic result was not available. Percentages were calculated based on non-missing values.

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