GILEAD | Medical Information

Epclusa® (sofosbuvir/velpatasvir) Use in People Who Inject Drugs

This document is in response to your request for information regarding the use of Epclusa® (sofosbuvir/velpatasvir [SOF/VEL]) for the treatment of chronic HCV in people who inject drugs (PWID), including patients receiving opioid substitution therapy (OST).

Some data may be outside of the US FDA-approved prescribing information. In providing this data, Gilead Sciences, Inc. is not making any representation as to its clinical relevance or to the use of any Gilead product(s). For information about the approved conditions of use of any Gilead drug product, please consult the FDA-approved prescribing information.

The full indication, important safety information, and boxed warnings are available at: www.gilead.com/-/media/files/pdfs/medicines/liver-disease/epclusa/epclusa_pi.

Summary

Product Labeling[1]

Based on data from the phase 2 trial SIMPLIFY, the safety and effectiveness of SOF/VEL in participants who self-reported injection drug use, including in those on concomitant MAT, were similar to the known safety and effectiveness profile of SOF/VEL. No dosage adjustment of SOF/VEL is recommended for PWID, including those on MAT for opioid use disorder.

Clinical Studies on SOF/VEL Use in PWID

In six clinical studies, treatment with SOF/VEL was evaluated in participants with HCV who reported IDU or receiving OST.[2-9]

- SVR12 rates ranged from 49% to 100% in clinical studies.[2-9]
- SVR12 rates were not associated with IDU within the past month with OAT use (P=0.095)[4] or baseline OAT use (P=0.33)[8] and did not differ between OST users and OST non-users (P=0.062).[9]
- The most common AEs (≥10%) reported were fatigue, headache, and nausea,[5] and rates of AEs were similar between OST users and OST non-users (78% vs 77%; P=0.79).[9]

Real-World Data on SOF/VEL Use in PWID

In five real-world studies, several of which included patients who had mental disorders and/or were homeless or incarcerated, patients who received SOF/VEL treatment and reported IDU or receiving OST achieved SVR12/24 at rates between 83.1% and 100%.[10-14]

Clinical Studies on SOF/VEL Use in PWID

Multicenter Study in India[2]

Study design and demographics

A randomized, multicenter trial in India evaluated whether 12 weeks of SOF/VEL plus tailored adherence support for HCV treatment among PWID could optimize outcomes (N=3000). Eligible participants had a history of IDU and no history of HCV treatment, and the primary outcome was SVR12. A prediction model was used to categorize participants as having a low risk of failure (n=2048 [68%]) or a high risk of failure (n=952 [32%]), and participants in each category received basic support, PN only, or PN + DOT, depending on the participant's estimated risk for failure. In the low-risk and high-risk groups, the median age was 31 and 27 years, respectively; 98% and 100% were cisgender males; 6% and 26% were experiencing homelessness in the past 3 months; 17% and 29% were ever incarcerated; 42% and 89% reported IDU in the past 3 months; 41% and 49% received medications for opioid use disorder in the past 6 months; and 76% and 75% reported harmful or hazardous alcohol use.

Efficacy

In the ITT analysis, SVR was 63% in the low-risk group and 49% in the high-risk group. There was no significant difference in SVR rates between participants in the high-risk group who received different levels of support, and SVR in the low-risk group was significantly higher in those who received PN + DOT vs basic support (adjusted relative risk, 1.10; *P*=0.04).

Safety data were not reported.

HERO Study[3]

Study design and demographics

A pragmatic, randomized, multicenter, clinical study compared outcomes between two patient-centered treatment models for the treatment of HCV in participants with active IDU in the US. Eligible participants were aged 18 to 70 years, had current HCV infection, and reported active IDU ≤90 days of screening. Participants were randomly assigned in a 1:1 ratio to the mDOT or PN group and were stratified by city, opioid treatment programs vs community health centers, and stage of liver disease (cirrhosis or Fibrosis-4 >3.25 vs no cirrhosis). All participants received 12 weeks of SOF/VEL in electronic blister packs, and the primary outcome was the proportion of participants in the PP population (participants who were randomized, initiated treatment, and did not cross over to a different treatment arm) who achieved SVR (HCV RNA ≤15 IU/mL) between 70 and 365 days after the end of treatment.

The baseline demographics of the 496 participants in the PP population were the following: male, 72.6%; median (IQR) age, 42.6 (35.3–53.7) years; White race, 63.6%; Hispanic ethnicity, 22.8%; participating in an opioid treatment program, 46.6%; injecting drugs >2 ×/day, 43.2%; last drug injection <5 weeks prior, 74.2%; and last injection in the past 3 months ≥30 days prior, 47.4%.

Efficacy

The SVR rate in the PP population was 92.7% (n/N=460/496; 95% CI: 90.5–95%), with an overall median adherence rate of 75%. A higher number of total adherent days was significantly associated with SVR in the PP population (aOR, 1.07; 95% CI: 1.04–1.1; *P*<0.001). The SVR rate was >90% in the PP population with as few as 42/84 total adherent days (50%). The number of consecutive missed treatment days was inversely associated with SVR in the PP population (aOR, 0.93; 95% CI: 0.91–0.96; *P*<0.001). The SVR rate was 85.25% among participants with ≥14 consecutive missed treatment days and 96.9% among those with <7 consecutive missed days (aOR, 0.19; 95% CI: 0.07–0.55; *P*=0.02).

Safety data were not reported.

STоP-C Study[4]

Study design and demographics

STоP-C was a prospective cohort study in Australia that assessed the efficacy and safety of 12 weeks of SOF/VEL treatment in incarcerated participants with HCV (N=324). Eligible participants were adults aged ≥18 years with or without detectable HCV RNA, and participants with detectable HCV RNA at enrollment or during study follow-up (incident infection) were eligible for treatment, regardless of HCV GT, stage of liver disease, or IDU. The primary outcome was SVR12, and secondary outcomes included treatment completion. The median (IQR) age was 32 (26–38) years, 306 participants (94%) were male, 58 (18%) had received previous treatment for HCV, 166 (51%) reported IDU within the past month of incarceration, 155/166 (93%) reported reusing any injection equipment after someone else had used it, and 14/166 (8%) were receiving OAT.

Efficacy

At the end of the study, 301 of the 324 participants who initiated SOF/VEL were due for SVR assessment, 201/301 participants (65%) had completed treatment, and 143/201 (69%) had completed SVR assessment. In the ITT population, which included participants who initiated SOF/VEL treatment and were due for SVR12 assessment by the end of the study (n=310), the SVR12 rate was 44% (95% CI: 39–50%). In the PP population, which included participants who completed treatment and had an SVR12 assessment (n=143), the SVR12 rate was 96% (95% CI: 91–98%); 6 participants (4%) did not achieve SVR12 due to reinfection (n=4) or treatment failure (n=2).

The ITT SVR12 and PP SVR12 rates among participants with IDU within the past month were 42% and 94%, respectively. A multivariate logistic regression analysis of the ITT population found that a longer duration of current incarceration was the only assessed factor associated with SVR12 (aOR per month, 1.03; 95% CI: 1.01–1.04; *P*<0.001). In the ITT population, there was no significant association between IDU within the past month (*P*=0.894), IDU within the past month with reusing injecting equipment after someone else had used it (*P*=0.931), or IDU with OAT use (*P*=0.095) and SVR12.

Safety data were not reported.

SIMPLIFY Study

Study design and demographics[5]

SIMPLIFY was an open-label, phase 4 study that assessed the efficacy and safety of SOF/VEL in HCV-infected participants reporting recent IDU from 19 sites in Australia, Canada, New Zealand, Norway, Switzerland, the United Kingdom, and the US (N=103). Participants received a weekly supply of SOF/VEL in an electronic blister pack with an integrated sensor grid for a 12-week course with continued follow-up visits through Week 36. The median (IQR) age was 48 (41–53) years, and 74 participants (72%) were male. All participants reported IDU in the past 6 months, 74% (n=76) reported IDU in the past 30 days, and 54% (n=56) reported using non-injecting drugs in the past 30 days.

Efficacy and safety

The SVR12 rate was 94% (97/103; 95% CI: 88–98%). Of the 100 participants who completed 12 weeks of SOF/VEL, 3 did not meet SVR12 (LTFU, n=2; reinfection, n=1). There were no cases of virological failure or relapse.[5]

No factors were determined to have an effect on SVR12, including the frequency or timing of IDU, baseline OST, stable housing situation, liver fibrosis, or frequency of alcohol consumption. Adherence (≥ or <90%) was also not a factor in achieving SVR12.[5] Additionally, in a SIMPLIFY substudy, SVR12 rates were not significantly different between participants with or without missed doses. There was a significant difference in SVR12, however, between participants who did and did not complete the 12-week treatment course (97% and 0%, respectively; $P<0.001$).[6]

Eighty-five participants (83%) experienced ≥1 AE. Most AEs were Grade 1 to 2 (n=78; 76%); 6 participants (6%) experienced a Grade 3 AE, and 1 participant (1%) experienced a Grade 4 AE. The most common AEs (≥10% of participants) were fatigue (22%), headache (18%), and nausea (14%). One death and 7 SAEs were reported.[5]

ANCHOR Study

Study design and demographics[7,8]

The ANCHOR study was a prospective, observational, single-center study that evaluated adherence to DAA treatment among PWID (ongoing IDU; N=100) and its effect on the achievement of SVR12. In addition to receiving 12 weeks of SOF/VEL treatment, participants were offered OAT with buprenorphine/naloxone. OAT could be discontinued if repeated UDS results were negative for buprenorphine, for study visit non-adherence, or due to participant preference. Adherence assessments included the following: HCV viral load at Week 4, interruptions of SOF/VEL treatment (≥3 consecutive days of missed SOF/VEL), number of 28-day medication bottles completed (3 bottles per 12-week treatment), and timing of the last SOF/VEL pill taken relative to Week 12 (of participants who completed all bottles of SOF/VEL). Imperfect adherence was defined as completion of HCV treatment ≥7 days after the expected treatment end date. At Weeks 0, 4, and 12, UDS and HRBS were obtained. Patients were monitored for HCV reinfection through Week 96.

Efficacy, utilization of OAT, and drug use[7,8]

Overall, 82% of participants (82/100) achieved SVR12. In the ITT population (n=93), 78% of participants achieved SVR12; in the PP population (n=82), 89% of participants achieved

SVR12. Virological failure occurred in 10% of participants in the ITT population and 11% in the PP population. In the overall population, 18 participants did not achieve SVR12, including 11 who experienced virologic relapse, 3 who were LTFU, 3 who died, and 1 who was incarcerated.

One-third of participants (33/100) were taking OAT at screening, and 79% of the participants (53/67) not initially on OAT began it during the study. During the study, 76 participants reported IDU, and UDS results were positive for opioids in 89 participants and for cocaine in 61 participants. Among those who began OAT during the study, the proportion of positive UDS results and HRBS scores significantly declined from baseline to the SVR12 timepoint (P=0.04 and P<0.001, respectively).

Adherence[8]

Eighty-four participants completed all dispensed bottles of SOF/VEL, 16 participants had a median (IQR) interruption of treatment of 8.5 (5–14.3) days, and 13 participants had a median HCV viral load >200 IU/mL at on-treatment Week 4 or later. Eighty-four percent of participants completed all 3 bottles of SOF/VEL, 66% attended all study visits, 63% completed their treatment within 7 days of the planned end, and 16% experienced treatment interruption.

Effects on SVR12[8]

The use of OAT at baseline (P=0.33), concomitant drug use during treatment (P>0.99), and incomplete daily adherence (P=0.35) were not associated with SVR12 achievement; however, SVR12 achievement was associated with completion of ≥2 medication bottles of SOF/VEL and OAT at Week 24. Among those who were not receiving OAT at baseline, the SVR12 rate was significantly higher in those who began and continued OAT (SVR12, 92%) than in those who never began OAT (SVR12, 64%; P=0.03), or those who began and discontinued OAT (SVR12, 63%; P=0.02). After an adjustment was made for SOF/VEL adherence, a logistic regression analysis of all participants revealed that the percentage of study visits where OAT was reported was significantly correlated with SVR12 achievement (P=0.008).

Opioid overdoses[8]

Thirteen participants experienced ≥1 overdose during the study, and 2 of these overdoses were fatal (1 was due to fentanyl, and the other was due to fentanyl, alprazolam, and ethanol). At Week 24, overdose was reported in 26% of participants who did not receive concomitant OAT and in 7% of participants who received OAT (P=0.007). A repeated measures analysis showed a significantly lower rate of overdose among those who were receiving OAT at study visits than among those who were not receiving OAT (risk ratio [standard error]: -1.14 [0.54]; P=0.04).

Combined Analysis of OST Users in the ION, ASTRAL, and POLARIS Studies[9]

Study designs and demographics

A post hoc analysis of 10 phase 3, multicenter, randomized studies was conducted to compare and evaluate treatment completion, adherence, SVR12 (HCV RNA <25 or <15 IU/mL), and safety among participants who received SOF-based HCV treatment with (n=194) or without (n=4549) concomitant OST. This analysis included the ION 1

through 3 (LDV/SOF ± RBV for 8, 12, or 24 weeks; patients with chronic HCV GT1), ASTRAL 1 through 3 (SOF/VEL for 12 weeks; HCV GT 1–6), and POLARIS 1 through 4 studies (SOF/VEL or SOF/VEL/VOX for 8 or 12 weeks; HCV GT 1–6).

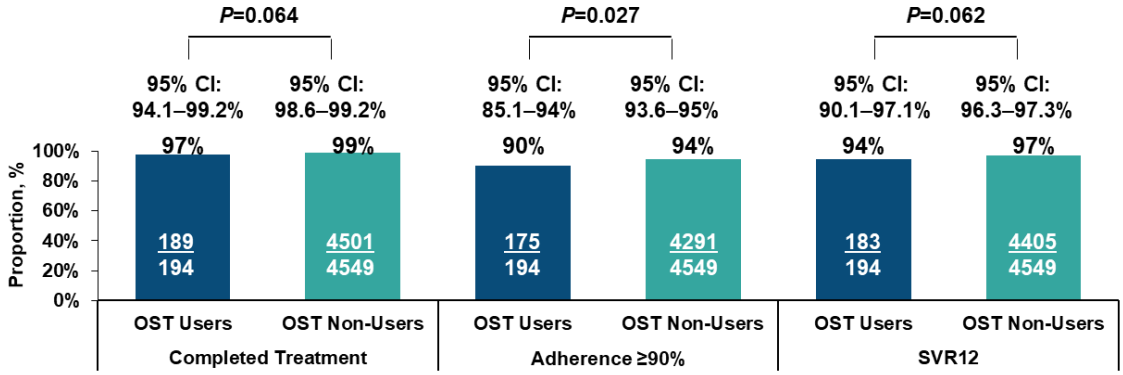
Table 1. Post Hoc Analysis: SOF-Based HCV Treatments (Grebely et al)[9]

Regimen, n (%)	OST Users (n=194)	OST Non-Users (n=4549)
LDV/SOF ± RBV for 8 weeks	8 (4)	423 (9)
LDV/SOF ± RBV for 12 weeks	32 (16)	835 (18)
LDV/SOF ± RBV for 24 weeks	13 (7)	641 (14)
SOF/VEL for 12 weeks	92 (47)	1643 (36)
SOF/VEL/VOX for 8 weeks	41 (21)	570 (13)
SOF/VEL/VOX for 12 weeks	8 (4)	437 (10)

Efficacy and adherence

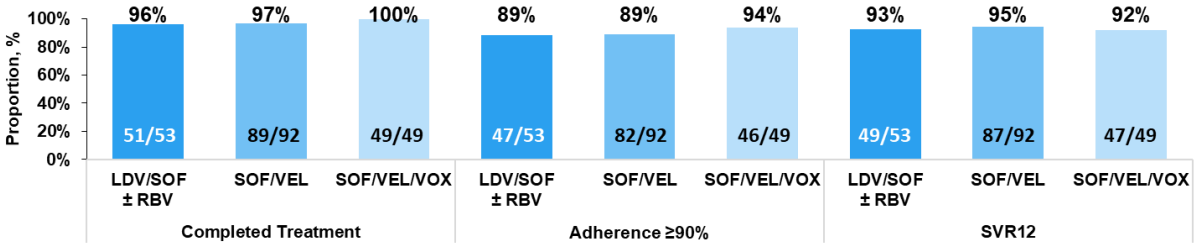
SVR12 rates and measures of adherence are shown in Figure 1. Among OST users, the reasons for discontinuation (n=5) that were reported were as follows: AEs (n=1), LTFU (n=1), withdrawal of consent (n=1), lack of efficacy (n=1), and non-compliance (n=1). Of the 19 OST users with <90% adherence, 12 met SVR12, and 7 did not meet SVR12 (LTFU, n=3; consent withdrawn, n=1; virologic breakthrough associated with non-adherence, n=1; discontinuation due to an AE, n=1; and discontinuation by an investigator due to non-adherence, n=1). Two participants were observed to have viral reinfection with a different HCV GT; however, neither participant was receiving OST at baseline.

Figure 1. Post Hoc Analysis: Treatment Completion, Adherence, and SVR12 According to OST Use (Grebely et al)[9]



SVR12 rates and measures of adherence by antiviral treatment are shown in Figure 2. In OST users, no significant differences in SVR12 rates were observed between participants who received methadone OST and those who received buprenorphine OST (95% vs 96%; *P*=1), between those who had cirrhosis and those who did not (99% vs 92%; *P*=0.089), or between those who had HCV GT 3 and those who had GT 1a (95% vs 95%; *P*=0.85). SVR12 rates were similar among OST users regardless of their baseline fibrosis stage (*P*-values not provided): F0, 88% (37/42); F1, 91.3% (21/23); F2, 97.8% (44/45); F3, 93.3% (28/30); and F4, 98% (50/51).

Figure 2. Post Hoc Analysis: Treatment Completion, Adherence, and SVR12 Among OST Users (n=194) According to Antiviral Treatment (Grebely et al)[9]



Safety

The proportion of AEs and SAEs observed was similar between OST users and non-users, and AEs were generally mild to moderate in severity.

Table 2. Post Hoc Analysis: Safety Outcomes (Grebely et al)[9]

Safety Outcomes, n (%)	OST Users (n=194)			OST Non-Users (n=4549)			*P*-Value
Overall AEs	152 (78)			3517 (77)			0.79
Overall SAEs	7 (4)			108 (2)			0.24
Safety Outcomes by HCV Treatment, n (%)	**LDV/SOF ± RBV (n=53)**	**SOF/VEL (n=92)**	**SOF/VEL/ VOX (n=49)**	**LDV/SOF ± RBV (n=1899)**	**SOF/VEL (n=1643)**	**SOF/VEL/ VOX (n=1007)**	***P*-Value**
AEs	47 (89)	68 (74)	37 (76)	1513 (80)	1251 (76)	753 (75)	NS[a]
SAEs	2 (4)	4 (4)	1 (2)	50 (3)	33 (2)	25 (3)	NS[a]
Most common AEs (>10%)							
Headache	12 (23)	20 (22)	8 (16)	443 (23)	450 (27)	269 (27)	–
Fatigue	19 (36)	18 (20)	11 (22)	556 (29)	364 (22)	222 (22)	–
Nausea	12 (23)	14 (15)	12 (25)	253 (13)	184 (11)	150 (15)	–
Diarrhea	4 (8)	7 (8)	5 (10)	151 (8)	110 (7)	183 (18)	–
Insomnia	5 (9)	5 (5)	3 (6)	232 (12)	112 (7)	59 (6)	–
Vomiting	4 (8)	6 (7)	6 (12)	60 (3)	42 (3)	24 (2)	–

Abbreviation: NS=not significant.
[a]NS for comparisons of each individual antiviral drug between OST users and OST non-users.

Real-World Data on SOF/VEL Use in PWID

Multinational Cohort[10]

An integrated real-world analysis conducted among 33 clinical cohorts from Australia, Canada, Europe, and the US evaluated the effectiveness of 12 weeks of SOF/VEL without RBV in HCV patients who were incarcerated, homeless, and/or had a mental health disorder (N=1888). Of the 985 patients (52%) who had a history of IDU, 371 patients (20%) were actively using drugs during the study; 405 patients (22%) had an unknown IDU history, and 498 patients (26%) had no history of IDU.

The SVR12/24 rate was 85% (1598/1888) in the overall population and 98% in the overall effectiveness population with active IDU. All homeless or incarcerated patients with active IDU achieved SVR12/24 and 97% of patients with a mental health disorder achieved SVR12/24.

European and Canadian Cohort[11]

A real-world analysis of 526 adult incarcerated patients from 20 clinical cohorts across six countries (Belgium, Canada, France, Italy, Portugal, and Spain) was performed to evaluate the effectiveness of 12 weeks of SOF/VEL. The effectiveness population (n=442) included patients with SVR12/24 data and excluded those with non-virological failure or failure due to unknown reasons (most were LTFU due to release from or transfer between prisons). Of the 236 patients (53.4%) in the effectiveness population with previous or current IDU, 53 patients (12%) had active IDU during the study; 169 patients (38.2%) had an unknown IDU history, and 16 patients (3.6%) did not have a history of IDU.

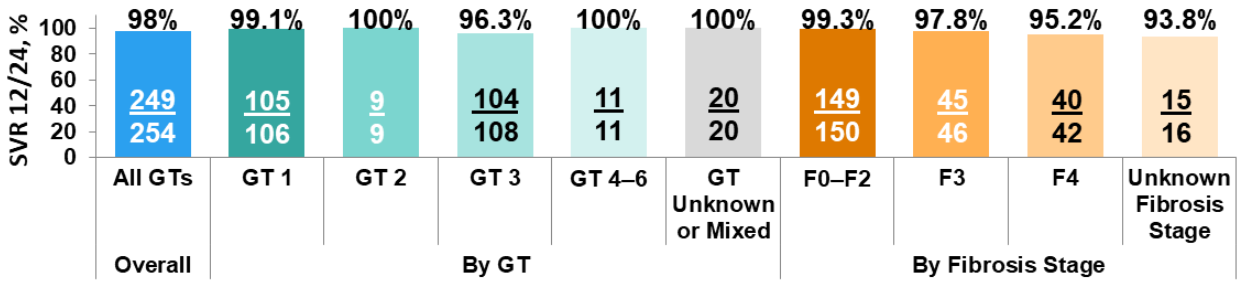
The SVR12/24 rate was 98.9% in the overall effectiveness population. All patients in the active IDU, antipsychotic drug use, and GT3 with active drug use groups achieved SVR12/24 (n=53/53, n=52/52, and n=22/22, respectively). No safety data were reported.

European, Canadian, and Australian Cohort[12]

A real-world analysis of adults with active IDU from 25 clinical cohorts across seven countries (Australia, Belgium, Canada, France, Germany, Italy, and Spain) evaluated the effectiveness of 12 weeks of SOF/VEL treatment and the feasibility of a test-and-treat strategy. Patients with a history of decompensation, those with prior NS5A-inhibitor exposure, those with HCC, and those who also used RBV were excluded. The endpoints included SVR12/24 in the effectiveness population (n=254), adherence (proportion of pills received, as evaluated by a physician), and duration of time between HCV diagnosis and initiation of SOF/VEL treatment.

The SVR12/24 rate was 98% in the overall effectiveness population and remained high when assessed by GT or by fibrosis stage (Figure 3). All patients who were homeless or incarcerated achieved SVR12/24 (n=64/64 and n=53/53, respectively); 97.3% of patients (181/186) with a mental health disorder and 95.3% of patients (41/43) with GT 3 and F3 or F4 achieved SVR12/24.

Figure 3. European, Canadian, and Australian Cohort: SVR12/24 Rates Overall, by GT, and by Fibrosis Stage (Effectiveness Population; Teti et al)[12]



The time from diagnosis of HCV to initiation of SOF/VEL treatment ranged from <1 day to >6 months (data were available for 187/254 patients in the effectiveness population). Most patients began SOF/VEL treatment within 6 months (84.5%; 158/187), and 16.6% began treatment within 1 week (31/187). SVR12/24 rates were high for each time period evaluated for time to treatment: <1 day, 100%; ≤1 week, 100%; ≤1 month, 98.7%; ≤3 months, 97.7%; ≤6 months, 97.5%; and >6 months, 100%.

Among patients with available adherence data in the effectiveness population (n=228), 219 patients (96%) had adherence rates ≥90%, with an SVR12/24 rate of 97.7%. Six patients (2.6%) had adherence rates <80%, and 9 patients (3.9%) had adherence rates <90%; all achieved SVR. No safety data were reported.

Canadian Multidisciplinary Care Center Cohort[13]

A real-world study conducted at an inner-city multidisciplinary care center evaluated the efficacy of HCV therapy (SOF/VEL, n=133; GLE/PIB, n=75) in patients with HCV who were actively using street fentanyl. The primary endpoint was SVR12. Medication adherence was verified weekly, and HCV therapy was administered in conjunction with OAT as appropriate. All eligible patients had documented fentanyl use within 1 week prior to HCV treatment initiation or a positive UDS for fentanyl at the time of HCV treatment initiation.

Of the 208 eligible patients, 11 patients discontinued from the study prematurely: 7 were non-adherent or LTFU, 3 withdrew from the study, and 1 patient died. Treatment discontinuations were not different between the treatment groups. At the time data were reported, 154 patients completed treatment, 138 had SVR data (SOF/VEL, n=79; GLE/PIB, n=59) and 16 were awaiting post-treatment HCV RNA results. At the time of the analysis, 76/79 of the patients (97.4%) who received SOF/VEL and 58/59 of the patients (98.5%) who received GLE/PIB had achieved SVR. All therapeutic failures were attributed to relapses (SOF/VEL, n=3; GLE/PIB, n=1). Safety data were not reported.

CHIME Project[14]

The CHIME Project was a prospective study that evaluated the safety and efficacy of SOF/VEL in participants with HCV infection and risk factors for treatment non-adherence, including IDU or unstable housing. The primary endpoint for the interim analysis was SVR12. Eligible participants were offered enrollment in a multidisciplinary program that provided medical, psychological, social, and addiction-related support. Participants were eligible to enroll if they had ≥6 months of documented HCV RNA of any GT, and active IDU (ongoing or within the previous 6 months) or active enrollment in OST programs. Participants were excluded if they had previous treatment with a DAA-based therapy for HCV, had decompensated liver disease, had active HCC, were HBsAg+ at the time of screening, or if the frequency of IDU was to an extent that the treating physician thought it would interfere with HCV treatment adherence. A total of 217/219 participants (99.1%) were active drug users and 176 (80.4%) had unstable housing. Of the participants with active drug use, 80% used opiates, 66% used amphetamines, 48% used fentanyl substance, 48% used cocaine, and 23% used benzodiazepines.

By the interim analysis date, 187 participants had initiated SOF/VEL treatment, with 148 having completed treatment. The SVR12 rate was 83.1% (123/148); 21 participants were awaiting results, and 4 participants had experienced virologic relapse. Of the 187 participants who had started SOV/VEL treatment, 5 died of overdose and 1 prematurely discontinued treatment.

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Abbreviations

AE=adverse event
aOR=adjusted odds ratio
DAA=direct-acting antiviral
DOT=directly observed therapy
F0/1/2/34=fibrosis stage 0, 1, 2, 3, or 4
GLE/PIB=glecaprevir/pibrentasvir
GT=genotype
HBsAg=hepatitis B surface antigen
HCC=hepatocellular carcinoma
HRBS=HIV Risk-Taking Behavior Scale
IDU=injection drug use
LDV=ledipasvir
LTFU=lost to follow-up
MAT=medication-assisted treatment
mDOT=modified direct observed therapy
NS5A=nonstructural protein 5A
OAT=opioid agonist therapy
OST=opioid substitution therapy
PN=patient navigation
PP=per protocol
PWID=people who inject drugs
RBV=ribavirin
SAE=serious adverse event
SOF=sofosbuvir
SVR=sustained virologic response
SVR12/24= sustained virologic response 12 or 24 weeks after end of treatment
UDS=urine drug screening
VEL=velpatasvir
VOX=voxilaprevir

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Epclusa US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/liver-disease/epclusa/epclusa_pi.

Follow-Up

For any additional questions, please contact Gilead Medical Information at:

☎1-866-MEDI-GSI (1-866-633-4474) or 🖱 www.askgileadmedical.com

Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or
🖱 www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🖱 www.accessdata.fda.gov/scripts/medwatch

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