GILEAD | Medical Information

Epclusa® (sofosbuvir/velpatasvir) Use in HCV Re-Infection

This document is in response to your request for information regarding the use of Epclusa® (sofosbuvir/velpatasvir [SOF/VEL]) in patients who have been re-infected with HCV.

This document includes content from, or references to, clinical practice guidelines, and inclusion should not be interpreted as a treatment recommendation or an endorsement of the guidelines by Gilead Sciences, Inc.

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

Product Labeling[1]

There is no information in the SOF/VEL product labeling about the use of SOF/VEL in treating HCV re-infection.

Clinical Data on SOF/VEL Use in HCV Re-Infection

SOF/VEL Use in HCV Re-Infection After DAA-Induced SVR[2]

Study design and demographics

A study conducted among participants in Taiwan who achieved SVR12 with DAA treatment between September 2013 and January 2021 and were subsequently re-infected with HCV assessed the effectiveness and tolerance of SOF/VEL (one tablet once daily for 12 weeks) vs GLE/PIB (three tablets once daily for 8 weeks) in the treatment of HCV re-infection. Re-infection was defined as having HCV viremia with an HCV genotype/subtype different than that from a prior diagnosis after SVR12 was achieved with DAA treatment. SVR12 (undetectable HCV RNA 12 weeks post treatment), tolerance, and safety were assessed.

Table 1. Baseline Demographics and Disease Characteristics (Liu et al)[2]

Key Demographics and Characteristics	SOF/VEL (n=12)	GLE/PIB (n=8)
Age, median (IQR), years	42 (31–51)	45 (28–57)
Male, n (%)	11 (91.7)	7 (87.5)

Key Demographics and Characteristics		SOF/VEL (n=12)	GLE/PIB (n=8)
Prior DAA regimen, n (%)	SOF/VEL	9 (75)	4 (50)
	SOF + RBV	1 (8.3)	1 (12.5)
	DCV + ASV	1 (8.3)	0
	SOF + DCV	1 (8.3)	0
	GLE/PIB	0	2 (25)
	EBR/GZR	0	1 (12.5)
HBV co-infection, n (%)		1 (8.3)	0
HIV co-infection, n (%)		10 (83.3)	6 (75)
HCV RNA, median (IQR), log_{10} IU/mL		6.75 (5.83–7.24)	7.06 (6.31–7.27)
HCV genotype/subtype, 1a/1b/2/3/6/1b + 2, n (%)		2 (16.7)/3 (25)/3 (25)/ 1 (8.3)/2 (16.7)/1 (8.3)	0/2 (25)/2 (25)/1 (12.5)/3 (37.5)/0

Abbreviations: ASV=asunaprevir; DCV=daclatasvir; EBR/GZR=elbasvir/grazoprevir; RBV=ribavirin.

Results

The overall median (IQR) duration of time from re-infection to retreatment was 2 (1–3.8) months. At Week 4, 11 participants (91.7%) in the SOF/VEL group and 6 participants (75%) in the GLE/PIB group had HCV RNA below the lower limit of quantitation. By the end of treatment (Week 12 for SOF/VEL and Week 8 for GLE/PIB), all participants had HCV RNA below the lower limit of quantification. Following treatment, 100% of participants in both groups achieved SVR4 and SVR12.

Four participants (33.3%) in the SOF/VEL group and 3 participants (37.5%) in the GLE/PIB group reported AEs, all of which were Grade 1 in severity: headache, n=2 (16.7%) and n=2 (25%), respectively; fatigue, n=2 (16.7%) and n=1 (12.5%); insomnia, n=2 (16.7%) and n=1 (12.5%); diarrhea, n=1 (8.3%) and n=1 (12.5%); and nausea, n=0 and n=1 (12.5%). No treatment discontinuations or interruptions, serious AEs, or deaths were reported.

One participant in each group experienced a Grade 2 laboratory abnormality of total bilirubin increased (1.5–3 × the upper limit of normal).

Clinical Practice Guidelines

The AASLD/IDSA Recommendations for Testing, Managing, and Treating Hepatitis C include treatment recommendations for patients re-infected with HCV for the PWID population:

- PWID found to be HCV re-infected should be retreated. Retreatment of a new re-infection should be as detailed for initial treatment of HCV infection.[3]

References

1. Enclosed. Gilead Sciences Inc, EPCLUSA® (sofosbuvir and velpatasvir) tablets, for oral use. US Prescribing Information. Foster City, CA.
2. Liu C, Liu C, Su T, Tseng T, Chen P, Kao J. Sofosbuvir/velpatasvir or glecaprevir/pibrentasvir for treating patients with hepatitis C virus reinfection following direct-acting antiviral-induced sustained virologic response. *Adv Dig Med.* 2023;10(1):34-42.
3. American Association for the Study of Liver Diseases (AASLD), Infectious Disease Society of America (IDSA). HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C. Available at: https://www.hcvguidelines.org. Last Updated: 19 December. 2023.

Abbreviations

AASLD/IDSA=American Association for the Study of Liver Diseases/Infectious Diseases Society of America
AE=adverse event
DAA=direct-acting antiviral
GLE=glecaprevir
PIB=pibrentasvir
PWID=people who inject drugs
SOF=sofosbuvir
SVR=sustained virologic response
SVR4/12=sustained virologic response 4/12 weeks after end of treatment
VEL=velpatasvir

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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