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GILEAD | Medical Information

Epclusa® (sofosbuvir/velpatasvir) Use in Patients Previously Treated With Glecaprevir/Pibrentasvir

This document is in response to your request for information regarding the use of Epclusa® (sofosbuvir/velpatasvir [SOF/VEL]) in patients previously treated with glecaprevir/pibrentasvir (GLE/PIB).

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.

Product Labeling[1]

In clinical trials in treatment-experienced adults, regimens contained PEG-IFNα/RBV with or without an HCV NS3/4A protease inhibitor (boceprevir, simeprevir, or TVR).

There is no information in the SOF/VEL product labeling about its use in patients previously treated with GLE/PIB.

Clinical Data on SOF/VEL Use in Patients Previously Treated With GLE/PIB

Case Reports

There are limitations in the interpretation of case reports. Case reports cannot be generalized. Unlike controlled clinical trials, causality cannot be inferred based on uncontrolled observational data. Additionally, incidence or prevalence cannot be estimated due to the lack of a representative population sample. Other limitations of case reports include the retrospective design and publication bias.[2]

Three patients infected with HCV who had not responded to prior DAA therapies were successfully retreated with SOF/VEL + RBV, with undetectable HCV RNA observed by Week 4 of treatment, and achievement of SVR24. None of the patients had cirrhosis or a history of hepatocellular carcinoma.[3]

Table 1. Baseline Demographics and Disease Characteristics (Nonomura et al)[3]

Key Demographics and Characteristics	Case 1	Case 2	Case 3
Age, years	58	51	68
Gender	Male	Male	Female

Key Demographics and Characteristics	Case 1	Case 2	Case 3
Prior DAA regimens	SOF + RBV, GLE/PIB	GLE/PIB	GLE/PIB
Prior IFN regimen	None	None	PEG-IFN + TVR + RBV
Outcome after latest DAA therapy	Relapse	Relapse	Breakthrough
HCV RNA viral load, log IU/mL	6.1	6.8	6.4
HCV genotype	1a	2a	3b

Case 1[3]

A 58-year-old male patient was treated with SOF/RBV for 12 weeks and achieved SVR24. Sixteen months following completion of SOF/RBV treatment, the patient relapsed and HCV reinfection was suspected due to illicit IV drug use. After discontinuing the use of illicit IV drugs, GLE/PIB was administered for 8 weeks and SVR12 was achieved; however, virologic relapse occurred 24 weeks following treatment completion. No RASs were detected. SOF/VEL + RBV was initiated and continued for 24 weeks. Hyperuricemia and mild elevations in liver transaminase levels were noted; however, no SAEs were reported. Forty-eight weeks after the patient completed therapy with SOF/VEL + RBV, HCV RNA remained undetectable.

Case 2[3]

A 51-year-old male patient with RASs in the NS5A region (L31M and P58S) received treatment with GLE/PIB for 8 weeks. Eleven weeks after completion of treatment, virologic relapse occurred. Following treatment failure, no additional RASs were detected. SOF/VEL + RBV was administered for 24 weeks and the patient achieved SVR24. No safety data, aside from weight loss of 5 kg during treatment, were reported.

Case 3[3]

A 68-year-old female patient, with a Fibrosis-4 index score >3.25 at baseline and a history of treatment failure with TVR + PEG-IFN + RBV initiated treatment with GLE/PIB. Virologic breakthrough occurred during Week 4 of treatment, and GLE/PIB was discontinued. Following treatment failure with GLE/PIB, ALT levels were elevated and indicated advanced fibrosis. Population sequencing identified an RAS in the NS5A region (Y93H). SOF/VEL + RBV was administered for 24 weeks and the patient achieved SVR24. Headache and mild pruritus occurred during treatment; however, no SAEs were reported.

References

1. Enclosed. Gilead Sciences Inc, EPCLUSA® (sofosbuvir and velpatasvir) tablets, for oral use. US Prescribing Information. Foster City, CA.
2. Nissen T, Wynn R. The Clinical Case Report: A Review of Its Merits and Limitations. *BMC Res Notes.* 2014;7:264.
3. Nonomura A, Tamori A, Hai H, et al. Sofosbuvir/Velpatasvir Plus Ribavirin Combination Therapy for Patients with Hepatitis C Virus Genotype 1a, 2a, or 3b after Glecaprevir/Pibrentasvir Therapy Failed. *Intern Med.* 2021. https://www.ncbi.nlm.nih.gov/pubmed/34024853

Abbreviations

DAA=direct-acting antiviral
GLE=glecaprevir
IFN=interferon
PEG=pegylated
PIB=pibrentasvir
RAS=resistance-associated substitution
RBV=ribavirin
SAE=serious adverse event
SOF=sofosbuvir
SVR12/24=sustained virologic response 12/24 weeks after end of treatment
TVR=telaprevir
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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