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Epclusa® (sofosbuvir/velpatasvir) Detectable HCV RNA During Therapy

This document is in response to your request for information regarding phase 3 studies in participants with detectable HCV RNA during therapy with Epclusa® (sofosbuvir/velpatasvir [SOF/VEL]).

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Detectable HCV RNA During SOF/VEL Therapy

ASTRAL-1, -2, and -3: SOF/VEL for 12 Weeks in GTs 1–6

The ASTRAL-1, -2, and -3 studies evaluated 12 weeks of SOF/VEL use in treatment-naive and treatment-experienced participants with HCV infection (GTs 1–6), with and without cirrhosis (N=1035). Treatment duration of SOF/VEL was fixed and not guided by response. On-treatment HCV RNA levels were assessed by the CAP/CTM assay with an LLoQ of 15 IU/mL. The primary endpoint for all trials was SVR12, defined as HCV RNA < LLoQ at 12 weeks after the end of treatment. Overall, 98% (1015/1035) of SOF/VEL-treated participants achieved SVR12 (>95% across all GTs).[1-3]

In a retrospective analysis, HCV RNA levels were evaluated to determine if early viral kinetics were predictive of SVR12. Across all GTs, there was a rapid decline in HCV RNA, with 91% of participants (937/1032) achieving HCV RNA < LLoQ by Week 4. As highlighted in Table 1, the likelihood of attaining SVR12 did not correlate with the virologic response at Week 4 or cirrhosis status.[4]

Table 1. ASTRAL-1, -2 and -3 Studies: SVR12 Rates by HCV RNA at Week 4 and Cirrhosis Status[4]

On-Treatment Week 4 HCV RNA	SVR12, % (n/N)		
	Overall	Cirrhotic	Non-Cirrhotic
< LLoQ	99 (921/933)	96 (186/194)	99 (733/737)
≥ LLoQ	99 (94/95)	100 (26/26)	99 (68/69)

The analysis also evaluated the concordance between SVR12 and SVR24. All of the 991 SOF/VEL-treated participants who achieved SVR12 also achieved SVR24.[4]

References

1. Enclosed. Gilead Sciences Inc, EPCLUSA® (sofosbuvir and velpatasvir) tablets, for oral use. US Prescribing Information. Foster City, CA.

2. Feld JJ, Jacobson IM, Hezode C, et al. Sofosbuvir and Velpatasvir for HCV Genotype 1, 2, 4, 5, and 6 Infection. *N Engl J Med.* 2015;373(27):2599-2607. http://www.ncbi.nlm.nih.gov/pubmed/26571066
3. Foster GR, Afdhal N, Roberts SK, et al. Sofosbuvir and Velpatasvir for HCV Genotype 2 and 3 Infection. *The New England Journal of Medicine.* 2015;373(27):2608-2617.
4. Alqahtani S, Zeuzem S, Bourgeois S, et al. On-Treatment HCV RNA as a Predictor of SVR12 in Patients with Genotype 1-6 HCV Infection Treated with Sofosbuvir/Velpatasvir for 12 Weeks: An Analysis of the ASTRAL-1, ASTRAL-2, and ASTRAL-3 Studies [Poster SAT-257]. Paper presented at: European Association for the Study of the Liver (EASL); 13-17 April, 2016; Barcelona, Spain.

Abbreviations

CAP/CTM=Roche COBAS Ampliprep/Cobas TaqMan HCV Test, Version 2.0
GT=genotype
LLoQ=lower limit of quantification
SOF=sofosbuvir
SVR12/24=sustained virologic response 12/24 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

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