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Epclusa® (sofosbuvir/velpatasvir) Use in HCV Genotypes 1 Through 6

This document is in response to your request for information regarding Epclusa® (sofosbuvir/velpatasvir [SOF/VEL]) in patients with HCV genotypes (GTs) 1 through 6.

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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.

Summary

Product Labeling[1]

SOF/VEL is indicated for the treatment of adult and pediatric patients 3 years of age and older with chronic HCV GT 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis and with decompensated cirrhosis for use in combination with RBV. Refer to the package insert for information on the recommended adult and pediatric dose.

Clinical Data on the Use of SOF/VEL in Patients With HCV GTs 1 Through 6

In the SVR10K real-world analysis (N=7027), 99% (n/N=6387/6461) achieved SVR. Overall SVR rates remained high among patients with GT 3 (98%), cirrhosis (99%), and GT 3 with cirrhosis (98%). Data on time from HCV diagnosis to treatment initiation were available for 68% of patients (n=4744), and 24% of those patients were treated within the first 30 days.[2]

A retrospective integrated analysis of the ASTRAL-1, -2, -3,[3,4] and -5,[5] POLARIS-2 and -3,[6,7] Russian and Swedish,[8] and Indian studies[9] was conducted to evaluate the efficacy and safety of 12 weeks of SOF/VEL in patients with HCV GTs 1 through 6 (n=1938). Patients with decompensated cirrhosis were excluded from this analysis. The overall SVR12 rate was 98%, and SVR12 rates were similar regardless of HCV GT, cirrhosis status, and treatment experience. The most common AEs experienced by ≥10% of patients were headache (24%), fatigue (19%), and nausea (10%).[10]

Clinical Data on the Use of SOF/VEL in HCV GTs 1 Through 6

SVR10K Study: Real-World Analysis[2]

Study design and demographics

A large, real-world analysis evaluated patient and treatment characteristics among patients from general and vulnerable populations (ie, people who inject drugs, homeless people, incarcerated people, and people with mental disorders) treated with SOF/VEL in 13 sites in

9 countries (ie, Brazil, Colombia, Hong Kong, Mexico, Singapore, Spain, Sweden, Taiwan, and the United Arab Emirates). Overall, 7027 patients who were ≥18 years of age, had no history of cirrhotic decompensation, and had no NS5A inhibitor exposure were included and received SOF/VEL without RBV for 12 weeks.

Table 1. SVR10K: Baseline Demographics and Disease Characteristics[2]

Key Demographics and Characteristics		Overall (N=7027)	Minimum Value [Region]	Maximum Value [Region]
Age, median (IQR), years		55.1 (46–64)	31.3 (27–52) [ME]	57 (48–66) [Asia]
Age ≥50 years, n (%) or %		4587 (66)	28 [ME]	71 [Asia, South Europe]
Male, n (%) or %		4564 (65)	51 [LATAM]	69 [ME, South Europe]
Cirrhosis, n (%) or %		1341 (21.5)	18 [Nordics]	33.9 [LATAM]
TE, n (%) or %		339 (5)	0 [ME]	11 [Nordics]
HCV GT, n (%) or %	GT 1	2125 (30.2)	15.3 [Nordics]	48.7 [ME]
	GT 2	1187 (16.9)	1.7 [ME]	25.8 [Nordics]
	GT 3	2117 (30.1)	14.4 [LATAM]	56.6 [Nordics]
Co-infection, n (%) or %	HIV	303 (4.5)	1.7 [ME]	14.8 [South Europe]
	HBV	216 (3.3)	0 [ME]	3 [Asia]
	HDV	6 (0.1)	–	0.2 [Asia]

Results

The overall SVR rate in the effectiveness population, which excluded patients without SVR status due to non-virologic or unknown reasons, was 99% and ranged from 97% to 100% across study sites. SVR rates remained high among patients with HCV GT 3 and cirrhosis (Table 2). Data on time from HCV diagnosis to treatment initiation were available for 68% of patients (n=4744), and 24% of those patients were treated within the first 30 days (Table 2). No safety data were reported.

Table 2. SVR10K: SVR (Effectiveness Population[a]) and Time to Treatment Initiation[2]

Outcomes		Overall	Minimum Value [Region]	Maximum Value [Region]
SVR (modified ITT), n (%) or %	Overall (n=6461)	6387 (99)	97 [Nordics]	100 [ME]
	GT 3	1989 (98)	96 [Nordics]	100 [ME, Asia]
	Cirrhosis	1246 (99)	96 [Nordics]	100 [ME, Asia]
	GT 3 and cirrhosis	406 (98)	93 [Nordics]	100 [ME, Asia]
Time from HCV diagnosis to treatment initiation (n=4744), %	<1 day	10.4	5.1 [LATAM]	17.8 [Asia]
	1–7 days	4.6	0 [ME]	11.8 [LATAM]
	8–30 days	8.9	1.5 [Nordics]	14.4 [South Europe]
	31–90 days	9.7	6 [Asia]	40.3 [ME]
	91–180 days	9.9	4.5 [Asia]	24.4 [ME]
	>180 days	56.7	13.4 [ME]	77 [Nordics]

[a]Effectiveness population excluded patients without SVR status due to non-virologic or unknown reasons.

Integrated Post Hoc Analysis

Study design and demographics

A retrospective integrated analysis of the ASTRAL-1, -2, -3,[3,4] and -5,[5] POLARIS-2 and -3,[6,7] Russian and Swedish,[8] and Indian studies[9] was conducted to evaluate the efficacy and safety of 12 weeks of SOF/VEL in patients with HCV GTs 1 through 6 (n=1938; Figure 1). Patients with decompensated cirrhosis were excluded from this analysis.[10]

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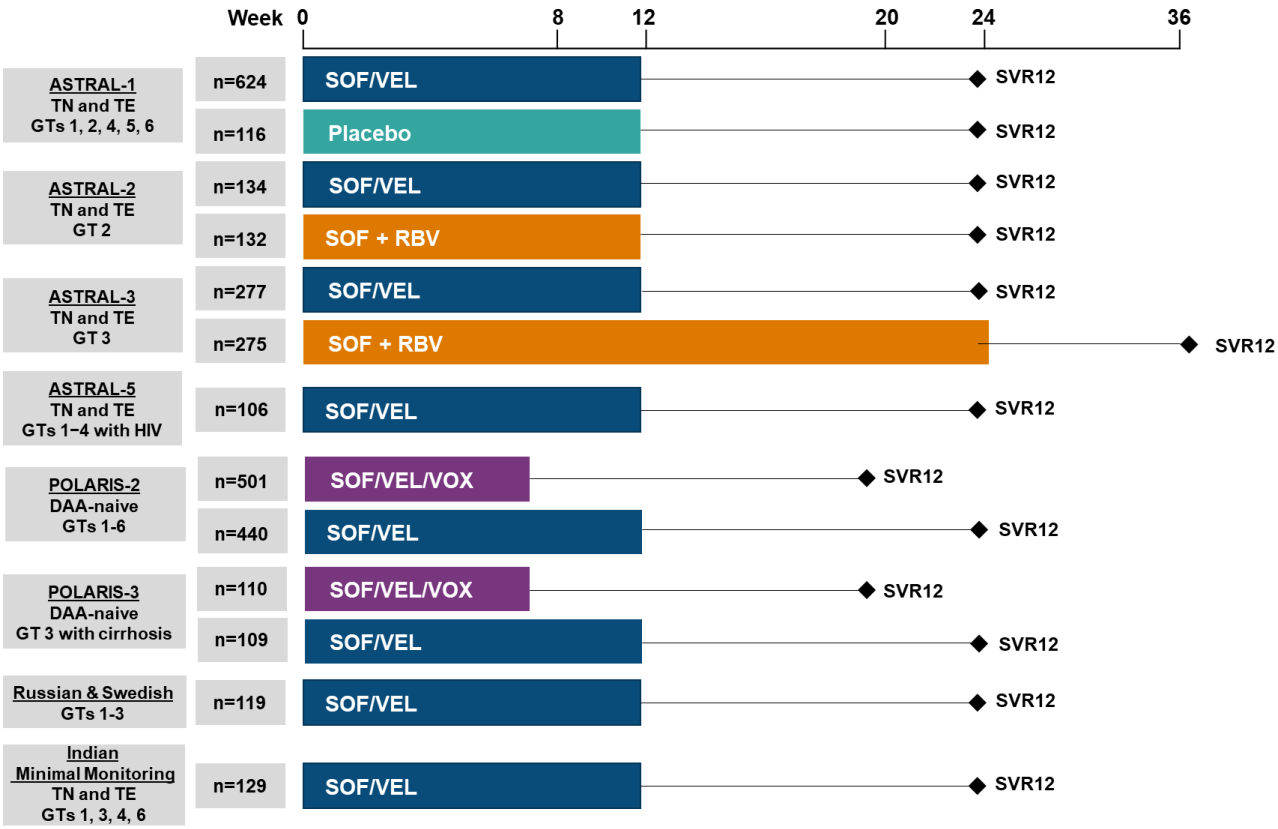
Among SOF/VEL-treated patients, the mean age was 52 years; 61% were male; 77%, 13%, 8%, and 2% were White, Asian, Black or African American, or other race, respectively; 38%, 16%, 31%, 10%, 2%, and 3% had HCV GTs 1, 2, 3, 4, 5, and 6, respectively; and 32%, 25%, 15%, and 28% had F0 to 1, F2, F3, and F4 fibrosis by FibroTest, respectively. Of the 494 TE patients (25%), 79% had previously been treated with interferon, 14% had received direct-acting antiviral-based treatment, and 7% had received other treatments.[10]

Figure 1. Integrated Post Hoc Analysis: Study Designs[10]

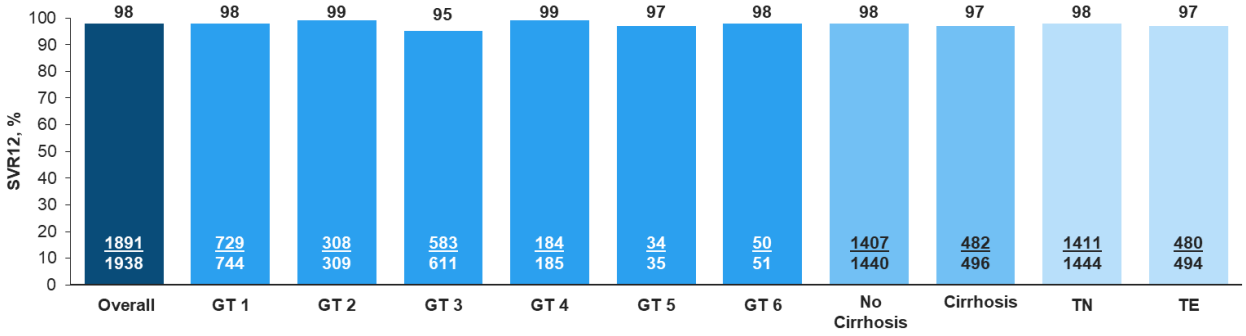


Abbreviation: VOX=voxilaprevir.

Efficacy[10]

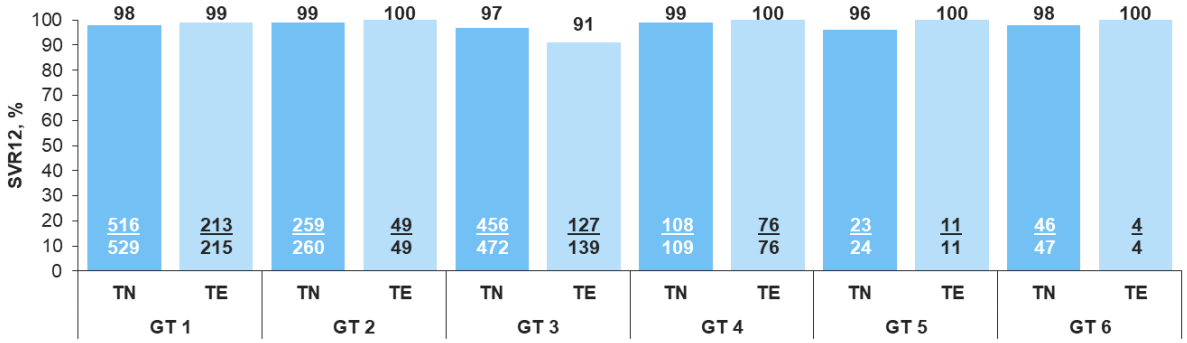
SVR12 was achieved in 98% of all patients, in 97% of patients with cirrhosis, and in 98% of patients without cirrhosis (Figure 2). SVR12 rates were similar between patients with and those without cirrhosis when grouped by GTs: GT 1 and no cirrhosis, 98% (n/N=555/578) vs cirrhosis, 99% (164/166); GT 2 and no cirrhosis, 99% (263/264) vs cirrhosis, 100% (44/44); GT 3 and no cirrhosis, 96% (359/375) vs cirrhosis, 95% (224/236); GT 4 and no cirrhosis, 99% (145/146) vs cirrhosis, 100% (39/39); GT 5 and no cirrhosis, 97% (28/29) vs cirrhosis, 100% (5/5); and GT 6 and no cirrhosis, 98% (44/45) vs cirrhosis, 100% (6/6).

Figure 2. Integrated Post Hoc Analysis: SVR12 Rates Overall and by Subgroups[10]



With the exception of patients with GT 3 (SVR12 rates: TN, 97%; TE, 91%), SVR12 rates were similar between patients who were TN and those who were TE when grouped by GT (Figure 3).

Figure 3. Integrated Post Hoc Analysis: SVR12 Rates by GT and Treatment History[10]



Similarly, GT 3 patients with baseline RASs had lower SVR12 rates than those without baseline RASs (92% [n/N=68/74] vs 98% [n=443/454]; no *P*-values provided). Among patients with other GTs, SVR12 rates were numerically similar between those with baseline RASs and those with no baseline RASs: GT 1, 98% (n/N=99/101) vs 99% (605/609), respectively; GT 2, 100% (182/182) vs 100% (121/121); GT 4, 100% (108/108) vs 99% (71/72); GT 5, 100% (3/3) vs 100% (31/31); and GT 6, 96% (26/27) vs 100% (25/25).

Safety[10]

No treatment-related SAEs were reported. The most common treatment-emergent AEs were headache, fatigue, and nausea (Table 3).

Table 3. Integrated Post Hoc Analysis: Safety Parameters[10]

Safety Parameters, n (%)		SOF/VEL Patients (n=1938)
AEs		1352 (70)
Treatment-emergent AEs occurring in ≥10% of patients	Headache	464 (24)
	Fatigue	376 (19)
	Nausea	199 (10)
SAEs		40 (2)
Grade 3 or 4 AEs		56 (3)
Grade 3 or 4 laboratory abnormalities		139 (7)
Discontinuations due to AEs		7 (<1)
Deaths		4 (<1)

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Abbreviations

AE=adverse event
GT=genotype
LATAM=Latin American region
ME=Middle East region
NS5A=nonstructural 5A protein
RAS=resistance associated substitution
RBV=ribavirin
SAE=serious adverse event
SOF=sofosbuvir
SVR=sustained virologic response
SVR12=sustained virologic response 12 weeks after end of treatment
TE=treatment-experienced
TN=treatment-naive
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

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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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