SOF/VEL/VOX FOR 8 OR 12 WEEKS RESULTS IN HIGH SVR12 RATES: AN INTEGRATED ANALYSIS OF THE POLARIS-1, POLARIS-2, POLARIS-3 AND POLARIS-4 STUDIES

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Background and Aims:
The once-daily fixed-dose combination tablet of sofosbuvir/velpatasvir/voxilaprevir (SOF/VEL/VOX) was evaluated for the treatment of genotype 1–6 HCV infection in four Phase 3 studies in direct acting antiviral (DAA)-experienced POLARIS-1 and POLARIS-4) and DAA-naïve (POLARIS-2 and POLARIS-3) patients with and without compensated cirrhosis. DAA-experienced patients received treatment for 12 weeks and DAA-naïve patients received treatment for 8 weeks. Overall SVR12 rates were >95% across all the studies. This post-hoc analysis assesses efficacy in patients with and without traditional negative predictors of response.

Methods:
This was a retrospective analysis of data from 1,056 patients treated with SOF/VEL/VOX in the Phase 3 studies.

Results:
Overall, 38% of patients had cirrhosis, 70% had HCV RNA ≥800,000 IU/mL, 59% of the DAA-experienced patients had received an NS5A inhibitor-containing regimen, 20% of the DAA-naïve patients had prior treatment failure with pegylated interferon+ribavirin, 12% were ≥65 years old and 10% were black. SVR12 rates for the DAA-naïve SOF/VEL/VOX 8 week and DAA experienced SOF/VEL/VOX 12 week subgroups were overall 95% & 97%; cirrhosis 94% and 95%; HCN RNA ≥800K 94% & 97%; age >65 96% and 99%; black 90% & 93% respectively. SVR12 rate for the DAA-naïve SOF/VEL/VOX 8 week prior PEG+RBV subgroup was 92%. SVR12 rate for the DAA experienced SOF/VEL/VOX 12 week prior NS5A Inhibitor subgroup was 96%.

Conclusions:
The POLARIS program enrolled a diverse patient population, including many with factors historically associated with treatment failure. Overall SVR12 rates for the DAA-naïve SOF/VEL/VOX 8 week and DAA experienced SOF/VEL/VOX 12 week subgroups were 95% and 97% respectively and in those with cirrhosis were 94% and 95% respectively.

Disclosure of Interest:
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