Sofosbuvir/Velpatasvir Single-Tablet Regimen for 12 Weeks in Patients Co-Infected with HCV and HIV-1: The Phase 3 ASTRAL-5 Study

**Introduction**

- **Sofosbuvir (SOF)**: 2nd-generation nucleotide polymerase inhibitor
- **Velpatasvir (VEL)**: non-nucleoside analog reverse-transcriptase inhibitor
- **TDF/FTC**: tenofovir disoproxil fumarate/emtricitabine
- **ABC/3TC**: abacavir/lamivudine

**Methods**

**Study Design**

- Open-label, single-arm, multicenter, Phase 3 study
- Broad inclusion criteria
- Liver-related disease remains a major cause of morbidity and mortality in patients coinfected with HCV and HIV-1
- Accelerated progression of liver disease
- Higher rates of cirrhosis, end-stage liver disease, and hepatocellular cancer
- Direct-acting antiviral (DAA) therapy that is effective across all HCV genotypes with limited drug-drug interactions with antiretroviral therapy (ART) is needed
- This Phase 3 study aimed to evaluate safety and efficacy of SOF/VEL in patients coinfected with HCV and HIV-1

**Results**

**HIV Baseline Characteristics**

- Mean CD4 count, cells/µL (range): 598 (183–1513)
- NRTI backbone
- TDF-based with boosted agent (RTV or COBI)
- TDF-based without boosted agent
- ABC/3TC-base
- ART use at baseline
- Pi (DRV, LPV or ATV)
- NNRTI (RPV)
- Integrate inhibitor (RAL or EVG)
- Other (>1 of the above classes)

**Adverse Events in ≥5%**

- Nausea
- Upper respiratory tract infection
- Diarrhea
- Fatigue
- Headache

**SVR12 by Baseline NS5A RAVs**

- 88% SVR12 with SOF/VEL
- 12% NS5A Class RAVs

**SVR12 by Cirrhosis or Prior Treatment**

- Cirrhosis Status: Treatment History

**Overall Safety**

- Patients, n (%) Total N=106
- AE
- Grade 3–4 AE
- Serious AE
- D/C due to AE
- Death
- Grade 3 or 4 laboratory abnormality
- HIV virologic rebound

**Conclusions**

- SOF/VEL treatment for 12 weeks resulted in 95% SVR12 rate in patients coinfected with HIV and HCV GT 1, 2, 3, and 4
- 100% SVR12 in patients with cirrhosis
- 97% SVR12 in patients who failed prior HCV therapy
- Presence of baseline NS5A RAVs did not impact SVR12
- Treatment with SOF/VEL for 12 weeks was safe and well tolerated with ART, including TDF-based with boosted regimens
- SOF/VEL for 12 weeks provides a simple, safe, and highly effective treatment for patients coinfected with HIV-1 and HCV

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