Global Real World Evidence of Sofosbuvir/Velpatasvir As a Simple, Effective Regimen for the Treatment of Chronic Hepatitis C Patients: Integrated Analysis of 12 Clinical Practice Cohorts

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Introduction

- The WHO estimates that 71 million people are chronically infected with hepatitis C (HCV) globally and has a goal to eliminate HCV by 2030.
- The availability of new pangenotypic regimens now provides healthcare practitioners worldwide with the opportunity to considerably simplify, and thereby facilitate, treatment access.
- SOFVEL is a pangenotypic, panprotease inhibitor (PI)-free, single tablet regimen (STR), offering a simplified treatment option to address this goal.
- This integrated analysis of real-world data from clinical practice cohorts representing a heterogeneous patient population evaluates the efficacy of SOFVEL for 12 weeks, without ribavirin (RBV), in patients with HCV across all genotypes (GT) and fibrosis stages, including patients with compensated cirrhosis (CC).

Methods

- **Collaboration Between 12 Cohorts in 7 Countries Across EU, North America and Canada**
  - 4,554 patients from 12 cohorts, including university hospitals, community centers, outpatient clinics and private practices.
  - Samples were included according to the treatment strategy according to local clinical practice.
  - GT-4 patients with CC or without CC (NC), treatment naïve (TN) or treatment experienced (TE), pegIFN/RBV-experienced, who started SOFVEL for 12 weeks were included.
  - Patients with a history of decompensation, prior NS5A inhibitor exposure, 2nd-generation NS5A inhibitor with interferon (IFN)-based treatment, or patients with cirrhosis (CC) were included.

Results

**Patient Characteristics**

- **SOF/VEL-Patients were included**
  - 4,554 patients from 12 cohorts, including university hospitals, community centers, outpatient clinics and private practices.

**SVR 12/24 Results by Genotype (Per Protocol)**

- **SVR 12/24 Results by Fibrosis Stage (Per Protocol)**

**SVR 12/24 Results by Genotype and Presence of Cirrhosis (Per Protocol)**

- **SVR 12/24 Results for Other Populations (Per Protocol)**

Conclusions

- **This is the largest real world cohort treated with SOFVEL**
- **High effectiveness of SOFVEL in a large diverse patient population, regardless of** – Genotype – Fibrosis stage – Treatment history (pegIFN + RBV + PIs)
- **407 patients did not achieve SVR12/24 (7.3%)**
  - Overall virological failure rate 1.5% (357/23414)
  - Overall virological failure rate 1.4% (805/57451)

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**Appendices**

- **Appendix A: Study Design and Data Sources**
  - **Appendix B: Study Design and Data Sources**
  - **Appendix C: Study Design and Data Sources**
  - **Appendix D: Study Design and Data Sources**

**Abbreviations**

- **IFN** interferon
- **PVP** pegylated-interferon
- **RBV** ribavirin
- **SOF** sofosbuvir
- **VEL** velpatasvir
- **SD** standard deviation
- **D/C** discontinuation
- **A. M. and A.**

**References**

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