

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

Alessandra Mangia¹; Scott Milligan²; Mandana Khalili³; Stefano Faggioli⁴; Stephen D Shafran⁵; Fabrice Carrat ⁶; Denis Ouzan⁷; George Papatheodoridis⁸; Alnoor Ramji⁹; Sergio M Borgia¹⁰; Heiner Wedemeyer¹¹; Losappio¹; Francisco Pérez¹²; Nicole Wick²; Dawn Fishbein¹³; Pietro Lampertico¹⁴; Karen Doucette⁵; Alex Thompson¹⁵; Dan Godfrey¹⁶; Michael Mertens¹⁷; Kim Vanstraelen¹⁷; Juan Turnes¹⁸

¹Ospedale Casa Sollievo Della Sofferenza, San Giovanni Rotondo, ITALY. ²Trio Health Analytics, La Jolla, CA, USA. ³University of California San Francisco/San Francisco General Hospital, CA, USA. ⁴Asst Papa Giovanni XXIII, Italy - Lombardia HCV Network ⁵University of Alberta, Canada. ⁶Sorbonne Université, Institut National de la santé et de la Recherche Médicale, Institut Pierre Louis d'Epidémiologie et de Santé Publique, Paris ; Assistance Publique - Hôpitaux de Paris, Hôpital Saint-Antoine, Unité de Santé Publique, Paris, France & ANRS CO22 HEPATHER France. ⁷Institut Arnault Tzanck, Saint-Laurent du Var, France. ⁸Department of Gastroenterology, Medical School of National and Kapodistrian University of Athens, Laiko General Hospital of Athens, Greece. ⁹University of British Columbia, Canada. ¹⁰Infectious Diseases, William Osler Health System, Brampton, Ontario, Canada. ¹¹Leberstiftungs-GmbH Deutschland, Hannover, Germany; Department of Gastroenterology and Hepatology, Essen University Hospital, Germany. ¹²Hospital Universitario NS Candelaria, Tenerife, Spain – HEPA-C Cohort. ¹³Medstar Health Research Institute, Washington DC, USA. ¹⁴CRC “A. M. and A. Migliavacca” Center for the Study of Liver Disease, Division of Gastroenterology and Hepatology, Fondazione IRCCS Cà Granda Ospedale Maggiore Policlinico, Università degli Studi di Milano, Milan, Italy. ¹⁵St Vincent’s Hospital, Melbourne, Australia. ¹⁶Medical Affairs, Gilead Sciences, Australia. ¹⁷Medical Affairs, Gilead Sciences Europe Ltd. U.K. ¹⁸Department of Gastroenterology and Hepatology, C.H.U. Pontevedra & IIS Galicia Sur, Spain – HEPA-C cohort.

Background & aims:

The WHO estimates that 71 million people are chronically infected with hepatitis C (HCV) globally and has a goal to eliminate HCV by 2030. SOF/VEL is a pangenotypic, panfibrotic, protease inhibitor (PI)-free, single duration, 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 SOF/VEL for 12 weeks, without ribavirin (RBV), in patients with HCV across all genotypes (GT) and fibrosis stages, including patients with compensated cirrhosis (CC).

Methods:

Data from 12 clinical practice cohorts across North America and EU, representing 7 countries, are included. Adults were treated according to local standards of care, with CC determined by the treating physician according to local clinical practice. Data on GT1-6 patients with CC or without CC (NC), treatment naïve (TN) or treatment

experienced (TE) [pegIFN+RBV ±PI], who completed SOF/VEL for 12 weeks prior to April 2018 were included. Patients with a history of decompensation, prior NS5A inhibitor exposure, treatment duration >12 weeks or addition of RBV were excluded. For patients who completed treatment and with virological outcome data available at abstract submission, sustained virological response (SVR; ≥12 weeks after end-of-treatment) was assessed.

Results:

Overall, 5541 patients with HCV GT1-6 were included. The median age was 54 years, 52.8% were male and GT distribution was as follows: 30% GT1, 30.% GT2, 33% GT3, 6.0% GT4-6, 1% mixed or unknown GT. CC was present in 1108 (20.7%) patients. 660 (12.4%) TE patients were included. 98.5% of patients (5134/5214) achieved SVR, with 98,7%%; 97,6%; 100% SVR respectively in NC, CC patients and patients with unknown cirrhotic status, and 97.8%, 98,3%, 96,4%% SVR respectively in pateints with current/historic IV drug use, , TE patients and GT3 patients with CC.

Conclusion:

Simplicity is key in reaching the WHO goals for HCV elimination. SOF/VEL for 12 weeks is a simple and highly effective regimen that cures HCV patients, irrespective of GT, cirrhosis status or treatment history, with a manageable drug interaction profile, which will contribute to the implementation of test & treat strategies.

Disclosure of Interest Statement: See example below:

The conference collaborators recognise the considerable contribution that industry partners make to professional and research activities. We also recognise the need for transparency of disclosure of potential conflicts of interest by acknowledging these relationships in publications and presentations.