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Sofosbuvir + Velpatasvir + Voxilaprevir in Daa Failure Patients with Cirrhosis. Final Results of the French Compassionate Use Program

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Abstract Text

Background: The combination sofosbuvir/velpatasvir/voxilaprevir (SOF/VEL/VOX) is approved for 12 weeks as a single tablet, once daily regimen, based on the phase 3 POLARIS studies for HCV patients who failed with DAA-containing regimens. However, few data from real-world cohorts exist. We report the efficacy and safety of SOF/VEL/VOX ± RBV in DAA failure patients with cirrhosis included in the French compassionate use program.

Methods: A total of 43 patients (31 males; mean age 58.7 years) were treated with SOF/VEL/VOX with RBV for 8 (n=1) or 12 weeks (n=8) or SOF/VEL/VOX for 12 weeks without RBV (n=34). Patients were chronically infected with HCV genotype 1 (1a n=7; 1b n=3; 1e n=2), 2 (n=4), 3 (3a n=17; 3b n=1), 4 (n=8), 5 (n=1) and 38 had cirrhosis (Median FibroScan 16 kPa, [13.5-24.9]). Among the 43 patients, 2 were liver transplant recipients, and 5 were co-infected with HIV. Previous treatment was SOF/LDV (n=15), SOF/DCV (n=21), 2D/3D (n=5), GZR/EBR (n=2). Baseline resistance testing was performed in 38 (88%) patients and NS5A, NS3, and NS5B RASs were present in 33, 7, and 0 patients, respectively.

Results: All patients (n=40) who achieved the end of treatment had undetectable HCV RNA. Among the 38 (88%) patients with available results at SVR4, SVR4 was observed in 37 (97.4%). Among the 33 (77%) patients with available results at SVR12, SVR12 was reported in 32 (97.0%). SVR12 will be available for all patients in November 2018. One patient (genotype 3a) experienced a relapse at SVR12 and resistance testing at the time of the relapse is ongoing. To date, two serious adverse events, hepatic decompensation and HCC, occurred in one patient classified as Child B8 at baseline.

Conclusion: In a real-world cohort, the combination SOF/VEL/VOX ± RBV for 8/12 weeks is effective in patients with cirrhosis who failed with DAA combination containing 1st generation NS5A inhibitor and/or protease inhibitor. This strategy is safe in patients with compensated cirrhosis. Final results of this cohort will be available in November 2018.

Disclosures

Christophe Hezode – Abbvie: Speaking and Teaching; Gilead: Speaking and Teaching; MSD: Speaking and Teaching

Dominique Larrey – ABBVIE: Consulting; GILEAD: Consulting; MSD: Consulting

Laurent Cotte – Gilead Sciences, Janssen, MSD, Abbvie: Grant/Research Support; ViiV Healthcare, Gilead Sciences: Advisory Committee or Review Panel

Jean Marc Combis – ABBVIE: Speaking and Teaching

Veronique Grando – gilead: Speaking and Teaching; abbvie: Speaking and Teaching; MSD: Speaking and Teaching

Luisa Stamm – Gilead Sciences: Employment; Gilead Sciences: Stock Shareholder

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