8 weeks treatment under real life conditions with Ledipasvir/Sofosbuvir in HIV co-infected treatment-naïve HCV genotype 1 patients demonstrates similar results to mono-infected HCV patients: data from the German Hepatitis C-Registry (DHC-R)

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Abstract Body

Introduction: Ledipasvir/Sofosbuvir (LDV/SOF) for 8-24 weeks is approved for the treatment of chronic hepatitis C. In the ION-3 study 8 weeks of LDV/SOF was non-inferior to 12 wks in previously untreated GT1 patients without cirrhosis. Although the number of patients eligible for 8 weeks according to the summary of product characteristics (SmPC) is high, a large proportion of patients still receives a longer treatment duration. One of the reasons might be the uncertainty whether 8 weeks treatment duration is sufficient in harder to cure populations as HIV co-infected patients, patients on opioid substitution treatment (OST) or older patients (> 70 yrs.). Aim of this analysis was to evaluate the virologic response rates of 8 wks treatment under real world conditions in these patients.

Methods: The German Hepatitis C registry is a national multicenter cohort. Patients are treated at the discretion of the physician. Data are collected by a web-based data system and confirmed by plausibility checks and on site monitoring. In this analysis data of patients with 8 or 12 wks treatment with LDV/SOF and available SVR12 data (data cut 2/2016) were included. Baseline characteristics, prior treatment history, safety and effectiveness were investigated.

Results: 831 (433 female) pts were treated for 8 weeks. The mean (SD) age was 50.2 (12.9) yrs. In 37% the fibrosis stage was evaluated by elastography (Fibroscan®), the mean (SD) stiffness value was 6.5 kPa (2.4). 874 pts reached the SVR 12 time point and were included in the analysis. Genotype distribution was 99.1% for GT1 and 0.9% for GT4. Baseline viral load was > 6 Mio IU/mL in 2,7%, 8,6% were treatment experienced and 2.5% had liver cirrhosis and were treated for 8 weeks despite these characteristics. The overall SVR 12 rate was 93% (ITT) and 98% (PP). 59 (8.8%) pts had HIV co-infection. SVR 12 in this group was 93.2% (ITT) and 96.6% (PP), only 2 viral relapses occurred. 72 pts received OST, only 1 pt developed viral relapse. 5 pts discontinued therapy and 5 were lost to follow up, thus, SVR12 was 84.7% (ITT) and 98.6% (PP) compared to 94.5% (ITT) and 97.9% (PP) without OST. 48 pts were >70 yrs. with SVR12 rates of 95.8% (ITT) and 97.9% (PP). 65 pts who were pretreated achieved SVR12 rates of 90.8% (ITT) and 95.2% (PP).

Conclusions: Under real world conditions, 8 wks LDV/SOF achieves very high SVR rates in heterogeneous groups like HIV co-infected pts and in other so called harder to cure populations.