**TELAPREVIR IN COMBINATION WITH PEGINTERFERON AND RIBAVIRIN IN FORMER INJECTION DRUG USERS WITH CHRONIC HEPATITIS C: FINDINGS OF THE OBSERVATIONAL INTEGRATE STUDY**

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**Background:** INTEGRATE is an observational, multicenter, prospective study evaluating the efficacy and safety of telaprevir with peginterferon-alfa and ribavirin (PR) in ex-people who inject drugs (ex-PWIDs) infected with HCV genotype 1. Few data currently exist for direct-acting antiviral agents in HCV-infected PWIDs and ex-PWIDs.

**Methods:** Eligible patients were treatment-naïve or prior-relapser ex-PWIDs with any fibrosis stage, receiving addiction treatment. Patients received telaprevir plus PR prescribed according to local labels. Sustained virologic response (SVR12) (HCV RNA <25IU/mL undetectable/detectable) was determined 12 weeks after treatment. Efficacy evaluable (EE) patients had no major protocol deviations and available follow-up data. Patient-reported adherence and health-related quality of life were also assessed.

**Results:** Of 46 patients in the intent-to-treat (ITT) population, 87% were male; 91% Caucasian; median age 44 years. Most patients were treatment-naïve (93%); had HCV GT1a (80%). More had F0–1 fibrosis (35%) than F2/F3/F4/unavailable (15/11/15/24%). 91% were receiving opioid substitution therapy, 98% attended an addiction center. 25/46 (54%) ITT patients achieved SVR12. SVR12 was achieved by 25/34 (74%) EE patients, including 1/1 (100%) prior relapser. Mean study treatment compliance (M-MASRI) among the ITT population was >90%. At follow-up, fewer patients reported anxiety/depression symptoms (HADS) (35/15%) than at baseline (43/33%), and median EQ-5D health outcomes score improved to 82 from 70 at baseline. The proportion of patients with an AUDIT (screen for excess drinking) score ≥8 remained unchanged from baseline. The most frequently-reported AEs were anemia (39%), thrombocytopenia (30%), fatigue (26%) and pruritus (22%). Serious AEs were reported in nine patients (24%); AEs led to treatment discontinuation in six patients (13%).

**Conclusion:** The efficacy in the EE patients, and the safety of telaprevir plus PR reported in this observational cohort of ex-PWIDs, are comparable with Phase 3 data for telaprevir in HCV mono-infected patients with no history of drug use.

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