Telaprevir-based triple-therapy in patients with chronic hepatitis C in Germany: a 12-week interim analysis of real-life data

Telaprevir (TVR)-based triple therapy in patients (pts) with chronic hepatitis C (HCV) in daily practice in Germany is investigated in this non-interventional study. Aims are the evaluation of the implementation of futility rules, as well as safety and efficacy of TVR-based therapy. This prospective, multi-center study investigates TVR-based therapy in therapy-naïve and pretreated pts with genotype 1 chronic HCV in Germany, including pts with HIV co-infection. Patients are treated with a combination of TVR, ribavirin and peg-interferon. This interim analysis includes data from the first 100 pts (12.5% of the planned total) at 32 sites completing 12 weeks (W) of treatment. 66% of pts were pretreated for HCV. 36.4% of pts with pre-treatment were prior relapers and 30.3% null or partial responders. Cirrhosis was present in 11% of all pts at baseline. HCV RNA levels below 800,000 IU/ml at baseline were present in 50% of pts. 67% of pts showed rapid virological response (RVR, undetectable HCV RNA at W4). Adherence to the futility rule (treatment stop if HCV-RNA >1000 IU/ml at W4) was 100% (N = 9). At W12, 91.4% of pts had undetectable HCV RNA. 57.7% of therapy-naïve pts and 86.4% of previous relapers were HCV-RNA negative at both W4 and 12 (70.8% in total). Only one patient achieving RVR at W4 suffered a virologic breakthrough. Nearly all pts (99%) had adverse events (AE) during the first 12W, 6% reported serious adverse events (SAE). AEs were mostly mild (63.9%) or moderate (34.6%) and frequently mentioned dry skin/pruritus (54%), gastrointestinal disorders (48%), anorectal discomfort (30%), rash (29%) and anemia (23%). Rash was mostly rated as mild or moderate (97.1%). An Hb decrease <12 g/dl (female) or <13 g/dl (male) was reported in 87% of pts. Mean Hb levels decreased from 14.8 g/dl at baseline to 10.6 g/dl at W12; Hb levels <8.5 g/dl at any time within the first 12W of treatment were present in 11% of anemia cases and 6.6% required transfusion. Only one patient received erythropoietin treatment. 2 cases each of anemia and rash were considered as SAE. These interim results suggest that TVR-based triple-therapy is efficient against GT1 chronic hepatitis C in a real life setting. Adherence to futility rules was confirmed in all patients. As observed in clinical trials, adverse events were reported frequently, including anemia and rash. As more data become available, results will be updated.