Telaprevir or boceprevir in HIV/HCV-1 co-infected patients in a real-life setting. Interim analysis (24 weeks). COINFECOVA-SEICV study

Minguez, Carlos1; Ortega, Enrique2; Flores, Juan3; Carmena, Jorge4; Masiá, Mar5; Montero, Marta6; Reus, Sergio7; Tornero, Carlos8; Jose Galindo, María9; Garcia-Deltoro, Miguel10; Amador, Concepción10; María Cuadrado, Jose11; Usó, Jorge1 and López-Aldeguer, Jose12

1Internal Medicine/Infectious Diseases Unit, Hospital General Universitario de Castellón, Castellón, Spain. 2Infectious Diseases, Consorcio Hospital General Universitario de Valencia, Valencia, Spain. 3Internal Medicine, Hospital Arnau de Vilanova, Valencia, Spain. 4Internal Medicine/Infectious Diseases Unit, Hospital Universitari Dr Peset, Valencia, Spain. 5Infectious Diseases, Hospital General Universitario de Elche, Elche, Spain. 6Infectious Diseases, Hospital Universitari i Politecnic La Fe, Valencia, Spain. 7Infectious Diseases, Hospital General Universitario de Alicante, Alicante, Spain. 8Internal Medicine, Hospital Francesc de Borja, Gandia, Spain. 9Infectious Diseases, Hospital Clinico Universitario de Valencia, Valencia, Spain. 10Infectious Diseases, Hospital Comarcal de la Marina Baixa, Villajoyosa, Spain. 11Infectious Diseases, Hospital Universitario San Juan de Alicante, Alicante, Spain. 12Internal Medicine, Hospital Universitari i Politècnic La Fe, Valencia, Spain.

Introduction: In general, HIV co-infected patients included in clinical trials evaluating the hepatitis C virus (HCV) therapy with telaprevir (TVR) or boceprevir (BOC) with advanced fibrosis, are scarce. We analyze data concerning the use of these drugs in a real-life clinical setting with patients affected by a more advanced degree of fibrosis in a Spanish cohort.

Methods: We evaluated safety and efficacy in an interim analysis encompassing the first 24 weeks of triple therapy with peginterferon (alfa-2a or alfa-2b), ribavirin and TVR or BOC in an observational, multicentre study. HIV/HCV genotype 1 co-infected patients beginning therapy from January 2012 to July 2013 were included.

Results: Enrolled patients were 155 (144 patients on TVR and 11 on BOC), average age was 47 years, 83% were male. With respect to HCV treatment, 44% were naïve, 13% relapsers, 17% partial responders, 21% null responders, and in seven patients, the previous response was unknown. All but three (98%) were under antiretroviral therapy (ART) (other than reverse transcriptase inhibitors, the backbone was raltegravir 43%, atazanavir 35%, and etravirine 28%). Median HCV-RNA at baseline was 6.1 log10, 54% were cirrhotic and 38% F3. At week 4, 93% of patients continued on therapy, 81% at w12, and 73% at w24. Virological failure was observed more frequently in: cirrhotic patients (19% [95% CI, 11–27]) vs F3 (12% [CI, 4–20]); patients with TT allele of the IL28B polymorphism (40% [CI, 18–61]) vs CT (21% [CI, 12–31]), or CC (2.2% [CI, –2–6]); previous null responders (37.5% [CI, 21–54]) vs partial responders (15.4% [CI, 1–29]), naïve (13% [CI, 5–21]) or relapers (0% [CI, 0–0]); and in patients with a genotype subtype 1a (23.6% [CI, 57–76]) vs 1b (8.1% [CI, 1–17]). Overall, 17% had virological failure and in 8% treatment was discontinued due to adverse events. Severe adverse events occurred in 30 patients (19%). Haematologic disorders were the most common type including severe anaemia in 12 (7.7%) patients. Erythropoietin was employed in 41 patients (26.4%) and 11 (7.1%) received blood transfusions. Nineteen patients (12.2%) were treated with G-CSF, and 17 (11%) with thrombopoietin-receptor agonists. Five patients died (3.2%), three due to hepatic decompensation, one due to pneumonia and one due to pulmonary hypertension.

Conclusions: In a real-life setting, therapy against HCV in co-infected patients with advanced liver fibrosis shows high virologic success at 24 weeks. However, frequent haematologic disorders are observed and a close monitoring and an intensive therapy are needed to optimize the results.