INTRODUCTION

REP 2139 is a nucleic acid polymer which blocks the assembly / secretion of HBV subviral particles and additionally binds to the small and large forms of HDAg (see Fig. 1). In the previous REP 301 study (NCT02233075) combination therapy with REP 2139-Ca and pegIFN achieved > 5 log reduction in HDV RNA in 12/12 patients and HDV RNA target not detected in 11/12 patients. Additionally, 5/12 patients achieved HBeAg reduction > 1 log from baseline and 5/12 patients achieved HBeAg loss. In the initial 1-year follow-up in the REP 301 and REP 301-LTF (NCT02876419) studies, 7/12 and 5/12 patients had undetectable HDV DNA and HBeAg. Evolving follow-up data is presented from the ongoing REP 301-LTF study.

RESULTS

AIMS

To evaluate the long term safety of combination therapy with REP 2139-Ca and pegIFN.
To evaluate the durability of the functional remission of HBV and HDV infection achieved in the REP 301 study.

METHODS

REP 301 patients (see Table 1) completing therapy were enrolled in the REP 301-LTF trial. Patients will be followed every 6 months for a period of 3 years. HDV RNA, HBV DNA, HBeAg and anti-HBs are followed every 6 months using standard assays (Robogene MK II RT-PCR, Abbott Realtime HBV, Abbott Architect). Median hepatic stiffness is evaluated by Fibroscan.

On treatment: Functional control achieved on treatment (HBeAg < 0.5 mIU/mL, HDV DNA = LLOQ).
On treatment: HBeAg reduction > 1 log from baseline but < 1 mIU/mL.
Follow-up: Functional remission of HBV infection (HBV DNA > 4000 U/mL) and HDV infection in functional remission.
Follow-up: Clinical benefit (normal liver enzymes and declining median hepatic stiffness).

DISCLOSURES

MB and AV are employees and shareholders in Replicor Inc.

REFERENCES

1. Quiet et al., Hepatology 2018.
2. Shamur et al., Hepatology 2017, 66: 504A.

CONTACT INFORMATION

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