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INCIDENCE OF RESISTANCE AFTER TREATMENT FOR TWO YEARS WITH EMTRICITABINE IN PATIENTS CHRONICALLY INFECTED WITH HEPATITIS B VIRUS

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BACKGROUND: Emtricitabine (Coviracil) is a nucleoside analogue reverse transcriptase inhibitor with potent activity against both hepatitis B virus (HBV) and HIV. In vitro, emtricitabine was shown to be up to 10 times more potent than lamivudine against HIV. One-year data from a Phase II study of emtricitabine in chronically-infected HBV patients (FTCB-102) showed a low rate of developing resistance mutations in the catalytic domain of the HBV polymerase (L526M±M550V/I) especially in the 200 mg once-a-day arm (6%; 95% CI [0–14]). We present here the 2-year data.

METHODS: FTCB-102 is a randomized, double-blind, dose ranging study comparing three doses of emtricitabine (25, 100, 200 mg once-a-day) for 1 year. After 1 year, eligible patients receive open-label emtricitabine 200 mg once-a-day for a second year. Monthly evaluations included HBV DNA quantification using the Digene HBV Test Hybrid Capture II assay with a lower limit of detection (LOD) of 4700 copies/ml. Genotypic analysis of the HBV polymerase (domains A–E) was performed by dideoxy sequencing on baseline, week-56 and week-96 samples with measurable DNA. All analyses are intent-to-treat.

RESULTS: Ninety-eight (98) patients were randomized to receive either 25, 100 or 200 mg emtricitabine once a-day for 1 year ($n=32$ or 33 per dose group). At baseline, 21% of the patients were HBeAg negative and 35% were emtricitabine-experienced. At 1 year, 94 patients were on drug, 47 % were below the LOD, and 16%, 13% and 6% developed resistance in the 25, 100 and 200 mg groups, respectively. At the end of 2 years, 40 patients (41%) had undetectable viraemia, 20 (20%) dropped out, 76% had normalized ALTs, 51% lost HBeAg and 29% seroconverted to HBeAb. Overall, the 2-year resistance

frequency was 25% (19% in the 200 mg once-a-day arm). Emtricitabine was well tolerated.

CONCLUSION: Emtricitabine produced a sustained virological response (41% <LOD at 2 years). At 2 years the overall incidence of L526M±M550V/I associated resistance was 25% and lower among patients receiving 200 mg for the duration of the study (19%), suggesting that more viral suppression with emtricitabine limits the emergence of resistant variants. This observation is consistent with results from an HIV clinical trial where the incidence of developing the M184V mutation after treatment with emtricitabine was low (21%). This profile could be especially interesting among patients co-infected with HBV and HIV.

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