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MIV-310 REDUCES MARKEDLY VIRAL LOAD IN PATIENTS WITH VIROLOGICAL FAILURE DESPITE MULTIPLE-DRUG THERAPY: RESULTS FROM A 4-WEEK PHASE II STUDY

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BACKGROUND: MIV-310 (3'-deoxy-3'-fluorothymidine) is a nucleoside analogue reverse transcriptase (RT) inhibitor, which exhibits potent in vitro efficacy against nucleoside reverse transcriptase inhibitor (NRTI) resistant viral strains.

METHODS: This Phase II pilot study included 15 patients failing an NRTI containing regimen with plasma HIV-1 RNA >1000 copies/ml and with >2 thymidine analogue mutations (TAMs). They received MIV-310, 7.5 mg once daily, in addition to their regimen during 4 weeks. Evaluation was performed weekly and 4 weeks after discontinuation of MIV-310.

RESULTS: At baseline the 15 patients had a median CD4 cells of 360 cells/mm³ and a median of HIV RNA plasma of 3.93 log₁₀. The median number of TAMs was 4 (2–5) with 100% of strains with T215Y/F at baseline. The overall median reduction in viral load after 4 weeks was –1.13 log₁₀ (n=15) with –1.88 log in patients with no stavudine and –0.57 in patients with stavudine included in the regimen. This difference suggests an interaction between MIV-310 and stavudine. At week 4, eight out of 11 patients who did not have stavudine included in their regimen harboured a viral load <400 copies/ml. The decrease of plasma HIV RNA was –1.59 log in patients with two TAMs, –1.69 log in patients with three TAMs, –1.92 log in patients with four TAMs and –1.18 log in patients with five TAMs. The HIV genotypic profile at week 4 was compared to that at baseline. No genetic changes in the RT coding regions have been seen between pre- and posttreatment HIV genotypes with 4 weeks of MIV-310 addition. Four weeks after MIV-310 discontinuation, the viral load rebounded to baseline values in all patients. MIV-310

was generally well tolerated. There was no withdrawal from therapy and no serious adverse events were reported. A transient mean increase in CD4 counts of 52 cells/mm³ was observed.

CONCLUSION: MIV-310 at 7.5 mg/day efficiently reduced viral load in patients with virological failure despite multiple resistance to NRTI. Further studies are being planned.

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