

Poster presentation

## Similar virological response rates for ART-naïve subjects starting K VX + LPV/r or TVD + LPV/r. Data from the prospective observational STAR cohort

E Wolf\*<sup>1</sup>, A Trein<sup>2</sup>, W Schmidt<sup>3</sup>, A Baumgarten<sup>4</sup>, H Jaeger<sup>5</sup> and HJ Stellbrink<sup>6</sup>

Address: <sup>1</sup>MUC Research, Munich, Germany, <sup>2</sup>HIV Center, Stuttgart, Germany, <sup>3</sup>Aerzteforum Seestraße, Berlin, Germany, <sup>4</sup>HIV-Practice Berlin Prenzlauerberg, Berlin, Germany, <sup>5</sup>HIV Research and Clinical Care Centre, Munich, Germany and <sup>6</sup>ICH (Infektionsmedizinisches Zentrum Hamburg), Hamburg, Germany

\* Corresponding author

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### Purpose of the study

Recently, an inferior virological response was observed in the ACTG 5202 trial for subjects with  $>10^5$  copies/ml of HIV-RNA randomised to abacavir + lamivudine (K VX) as opposed to tenofovir + emtricitabine (TVD), each plus efavirenz or atazanavir/r. In contrast, the HEAT study using lopinavir/ritonavir (LPV/r) together with TVD or K VX reported similar outcomes for both nucleoside analogue fixed-drug combinations. We analysed data from the STAR cohort, a German prospective, multicentre, observational study, which includes HIV+ patients starting with a regime containing LPV/r, for differences in antiviral response between the nucleoside analogue regimens.

### Methods

Virological and immunological treatment outcomes (time to  $<50$  copies/mL, % with viral load (VL)  $<50$  copies/ml, and time to  $>500$  CD4 cells/ $\mu$ L) in the groups receiving K VX or TVD were evaluated using on-treatment (OT), intent-to-treat (ITT), Kaplan-Meier and Cox PH regression analyses.

### Summary of results

A total of 801 ART-naïve pts (704 men) were included. Median age was 40 years (range: 20–76). 113 received K VX and 563 TVD. Median baseline CD4 cell count was not significantly different between the groups (K VX 238 vs. TVD 191/ $\mu$ L), whereas median viral load (VL) was significantly higher in the K VX than in the TVD group (5.3 vs.

5.1  $\log_{10}$  cop./ml,  $p = 0.01$ ). Median follow-up time was 21 weeks in both groups. At 24 weeks, 63% in the K VX group and 67% in the TVD group had a VL  $<50$  cop./mL (OT; ITT: 62% of K VX and 63% of TVD patients,  $p = ns$ ). Median changes in CD4 cells were +192/ $\mu$ L in K VX and +170/ $\mu$ L in TVD treated pts;  $p = ns$ . When analysing pts with  $>10^5$  or  $\leq 10^5$  cop./ml separately, there was no difference in response between K VX and TVD use in either group (57% vs. 54% and 67% vs. 80%, respectively,  $p = ns$ ).

In the Kaplan-Meier analysis, the median time to a confirmed VL of  $<50$  copies/mL was 25 weeks in the K VX and 24 weeks in the TVD group. Results of Cox PH analysis adjusting for baseline VL and CD4 confirmed that VL outcomes did not differ significantly if K VX or TVD was used.

Time to a confirmed CD4 count above 500/ $\mu$ L was 54 weeks in K VX and 83 weeks in TVD pts ( $p = ns$ ).

### Conclusion

This prospective non-interventional study so far fails to show a difference in antiviral response between subjects using K VX or TVD in conjunction with LPV/r adjusted for baseline VL and CD4 cells. The lack of a significant difference for K VX or TVD use confirms the results of the HEAT study in an observational setting.