PA-023 ASSESSMENT OF SAFETY PARAMETERS FOLLOWING REPEATED ARTEMISIN-BASED TREATMENTS OF MALARIA-INFECTED PATIENT LIVING IN ENDEMIC AREA OF BURKINA FASO

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Background Artemisinin-based combination therapies (ACTs) constitute the worldwide recommended antimalarial drug as first-line treatment of uncomplicated malaria. However, the safety of repeated administration of a given ACT is poorly documented. The aim of this study was to evaluate the safety of repeated administration of ACTs in malaria patients over a period of 2 years.

Methods A randomised, open-label phase IIIb/IV comparative three arms trial comparing pyronaridine tetraphosphate/artesunate (PA), dihydroartemisinine-pipéraquine (DHA-PQP) and artesunate-amodiaquine (ASAQ) was carried out in Burkina Faso site as part of the WANECAM (West African Network for Clinical Trials of Antimalarial Drugs) global study. The study involved patients from 6 months of age presenting with uncomplicated malaria (fever/history of fever and *Plasmodium* spp. density <200,000). The patients were treated repeatedly with the same ACT they were assigned to at enrolment. Safety assessments consisted with electrocardiographic and laboratory evaluations.

Results A total of 763 participants with uncomplicated microscopically confirmed *Plasmodium* spp. malaria were included. The proportion in ASAQ treated patients with creatinin abnormal value did not differ significantly between episode 1 and repeated malaria episodes (16.14% versus 13.98%, p=0.31). The proportion of patients with abnormal value of ALAT decreased significantly from baseline (25/234 versus 16/787, p< 0.01), but there is no difference in haemoglobin mean between the different episode (p>0.05) within each treatment arms. No evidence was found in the risk of QTc interval prolongation during repeated treatment in any arm.

Conclusions The findings showed that safety was similar on first malaria treatment versus retreatment of subsequent episodes. The safety parameters were also comparable between the 3 treatment arms. These results support the repeated use of the three ACTs in uncomplicated malaria patients in Burkina Faso.