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Abstract of Study:

**Disease Burden**

According to the WHO (2015) Malaria is one of the most important infectious diseases which threatens about 3.2 billion people; almost half of the world's population. Plasmodium falciparum (P. falciparum) malaria is a major cause of morbidity and mortality in Africa. Siaya County in Western Kenya is holoendemic for malaria. At the Siaya Hospital outpatient department alone, data abstraction shows 2000-4000 cases of uncomplicated malaria seen at the facility annually.

**Available remedies**

Artemisinin-based combination therapies (ACTs) such as Coartem®/Riamet® and Eurartesim®, are current standard-of-care for P. falciparum malaria. Artemisinin produces rapid clearance of parasitemia and resolution of symptoms by reducing parasite number by 100- to 1000-fold per asexual cycle of the parasite. Artemisinin and its derivatives are rapidly eliminated. It is therefore given in combination with 4-aminoquinoline drugs which have a longer half-life. This requires a three day course of treatment.

**Emergence of resistance**

Recent studies showed that artemisinin resistance extends over more of Southeast Asia than had previously been known, and is now present close to the border with India (Menard et al 2016). If widespread artemisinin drug resistance was to occur, malaria pharmacotherapy would be severely impaired. This finding signifies that spread of resistance is inevitable, thus there is urgent need for new antimalarials with new mechanism of actions (Tun et al 2015).

Secondly, evidence suggests that compliance to this 3-day regimen is low, thereby reducing Treatment effectiveness. New drug combinations are required. Particularly, effective single dose combination treatments will likely improve effectiveness; reduce likelihood of development of drug resistance.

Study Title:

**A Phase 2 interventional, multicenter, randomized open-label study to determine the effective and tolerable dose of KAF156 and Lumefantrine Solid Dispersion Formulation in combination, given once daily for 1, 2 and 3-days to adults and children with uncomplicated Plasmodium falciparum malaria.**

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