Ramachandra Sangana, Bakary Fofana, Rella Zoleko Manego, Sodiomon Bienvenu Sirima, Andre Toure Offianan, Jean Bosco Ouedraogo, Mulenge Kilowele, Anne Claire Marrast, Myriam El-Gaaloul, Celine Risterucci, Guoqin Su, Gen Zhu, Jared Thornton, Hira Choudhury, Jayant Sancheti, Cornelis Winnips, Issaka Sagara, and Zhiyan Qian

Pharmacokinetics of ganaplacide and lumefantrine in a pediatric population with *Plasmodium falciparum* uncomplicated malaria, treated with ganaplacide plus lumefantrine solid dispersion formulation: analysis of data from KALUMI, a multinational Phase 2 study.

Additional file 2

Summary statistics of plasma PK parameters for ganaplacide and lumefantrine - Cohort 1 (PK analysis set – partial food compliance)

Treatment group	Analyte	PK parameter (unit)	n	Geo-mean (CV% Geo-mean)
Ganaplacide plus lumefantrine-SDF	Ganaplacide	Day 1 AUC_{0-24h} (h*ng/mL)	14	10500 (61.9)
N=43		Day 3 AUC_{0-24h} (h*ng/mL)	41	19700 (62)
		Day 3 AUC_{inf} (h*ng/mL)	20	47600 (67.3)
		Day 1 AUC_{last} (h*ng/mL)	26	11800 (58.1)
		Day 3 AUC_{last} (h*ng/mL)	41	43600 (66.5)
		Day 1 C_{max} (ng/mL)	26	707 (66.9)
		Day 3 C_{max} (ng/mL)	41	1160 (68.3)
		$t_{1/2}$ (h)	20	20.9 (16.5)
		Day 1 t_{max} (h)[1]	26	5.88 (1.98-24)
		Day 3 t_{max} (h)[1]	41	3.05 (0-23.5)
		C_{168h} (ng/mL)	43	22.4 (122.8)
		C_{168h} (ng/mL)[2]	43	36.5 (54.9)
	Lumefantrine	Day 1 AUC_{0-24h} (h*ng/mL)	15	122000 (151.5)
		Day 3 AUC_{0-24h} (h*ng/mL)	41	378000 (55.7)
		Day 3 AUC_{inf} (h*ng/mL)	9	1090000 (58.3)
		Day 1 AUC_{last} (h*ng/mL)	26	114000 (152.6)
		Day 3 AUC_{last} (h*ng/mL)	41	960000 (66.6)
		Day 1 C_{max} (ng/mL)	26	7000 (143.5)
		Day 3 C_{max} (ng/mL)	41	20900 (57.2)
		$t_{1/2}$ (h)	9	27.7 (23.7)
		Day 1 t_{max} (h)[1]	26	6.01 (2-24.7)
		Day 3 t_{max} (h)[1]	41	5.67 (0-23.5)
		C_{168h} (ng/mL)	43	1330 (105.9)
		C_{168h} (ng/mL)[2]	43	1730 (1340)
Artemether-lumefantrine	Lumefantrine	C_{max} (ng/mL)[3]	53	6510 (63.3)
N=69		C_{168h} (ng/mL)	65	438 (80.9)
		C_{168h} (ng/mL)[2]	65	555 (407)

n = number of evaluable patients.

CV% geo-mean=(sqrt (exp (variance for log transformed data)-1))*100.

For the geometric mean calculation of C_{168h} and C_{max} of artemether-lumefantrine, below limit of quantification values are included as lower limit of quantification/2 (lower limit of quantification for ganaplacide is 5 ng/mL and for lumefantrine is 50 ng/mL).

Data from the PK analysis set - partial food compliance were included: ganaplacide plus lumefantrine-SDF patients who were compliant to meal criteria (within 30 minutes of drug administration and took at least 70% of the standard meal) on Day 2 and Day 3. Data issues, treatment discontinuations, patients with limited samples and patients who vomited twice after drug administration were excluded.

[1]Median (min - max) is presented for the parameter.

[2]Arithmetic mean (SD) is presented for the parameter.

[3]For artemether-lumefantrine group, concentration at 68h is considered as C_{max}.