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 3

Summary statistics of plasma PK parameters for ganaplacide and lumefantrine - Cohort 2 (PK analysis set – partial food compliance)

Treatment group	Analyte	PK parameter (unit)	n	Geo-mean (CV% Geo-mean)
Ganaplacide plus lumefantrine-SDF N=26	Ganaplacide	Day 3 AUC_{0-24h} (h*ng/mL)	26	11800 (61.5)
		Day 3 AUC_{inf} (h*ng/mL)	17	33600 (42.7)
		Day 3 AUC_{last} (h*ng/mL)	26	25800 (78.6)
		Day 3 C_{max} (ng/mL)	26	722 (59.4)
		$t_{1/2}$ (h)	17	19.6 (16.2)
		Day 3 t_{max} (h)[1]	26	2.95 (0-23.5)
		C_{168h} (ng/mL)	26	11.7 (85.7)
		C_{168h} (ng/mL)[2]	26	14.3 (9.74)
	Lumefantrine	Day 3 AUC_{0-24h} (h*ng/mL)	26	153000 (152.9)
		Day 3 AUC_{inf} (h*ng/mL)	5	684000 (106.1)
		Day 3 AUC_{last} (h*ng/mL)	26	391000 (212.7)
		Day 3 C_{max} (ng/mL)	26	8950 (151.9)
		$t_{1/2}$ (h)	5	33.3 (27.8)
		Day 3 t_{max} (h)[1]	26	6.05 (0-24.4)
		C_{168h} (ng/mL)	26	575 (150.8)
		C_{168h} (ng/mL)[2]	26	824 (607)
Artemether-lumefantrine N=39	Lumefantrine	C_{max} (ng/mL)[3]	31	3300 (142)
		C_{168h} (ng/mL)	35	297 (89.1)
		C_{168h} (ng/mL)[2]	35	387 (323)

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}.