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SUDA LTD

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ASX Release

Outstanding results from ArTiMist™ Phase III clinical study confirmed in the final report

- **Sub-lingual ArTiMist™ superior to intra-venous (IV) quinine.**
- **95.6% parasitological success rate for ArTiMist™ patients vs. 40.6% for IV quinine patients (p<0.005). Secondary efficacy parameters also present statistically significant differences between the two treatments (p<0.005) in favour of ArTiMist™.**
- **Results support ArTiMist™ as a rapid and effective treatment for young children.**

SUDA Ltd. (ASX: SUDA) confirms receipt of the final report relating to ART004: a Phase III, randomised, open labelled, active controlled, multi-centre, superiority trial of ArTiMist™ versus intravenous quinine in children with severe or complicated falciparum malaria, or uncomplicated falciparum malaria with gastrointestinal complications. The final report confirmed the previously published data on the significant superiority of sub-lingual ArTiMist™ in the reduction of the parasitic count within 24 hours when compared to IV quinine and statistically significant differences in efficacy between the two treatments.

The final report confirms 95.6% of the patients treated with ArTiMist™ had parasite count reduced by ≥90% within 24 hours versus 40.6% of the patients treated with IV quinine. The secondary efficacy parameters PCT, PRR_{24}, PCT_{50}, PCT_{90} demonstrated a statistically significant difference (p<0.005) overall between the treatments in both efficacy populations (Modified Intention to Treat (MITT[1]) and Per Protocol (PP)).

These results provide a compelling argument for the potential use of ArTiMist™ as an early interventional treatment for children suffering with the aforementioned form of malaria that can turn deadly within a very short period of time, especially for those children that are under the age of 5. Many of these children live in rural areas where local medical centres do not always have IV drugs or trained medical personnel able to insert an IV line. It also negates the risk of infections from needle use and

[1] *MITT population included all randomised patients who had received at least 1 dose of study medication and had evaluable parasite count at 24hrs after first dosing*

does not require cold chain storage. Moreover, it is not necessary to intake fatty food for maximum effect and can be administered to comatose children. ArTiMist™ addresses a wider patient population that includes those children that cannot swallow (tablet or other) or are vomiting and/or suffer with diarrhoea making the use of suppositories unsuitable.

SUDA's management believes that ArTiMist™ has the potential to be an effective pre-referral medication, and could significantly reduce mortality and reduce or eliminate the potential adverse effects suffered by children, particularly within the first 24 hours of infection. We remain of the opinion that ArTiMist™ could play a pivotal role in the global Rollback Malaria Program.

As previously stated, we are working with various groups to finalise the development and regulatory aspects of the project in order to bring ArTiMist™ to market in the most effective way and also identify a commercially acceptable trade sale opportunity.

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About ArTiMist™

ArTiMist™ is a patented, artemether-based, sublingual spray designed to treat children with severe or complicated malaria or uncomplicated *falciparum* malaria with GI complications (vomiting and diarrhoea) .

About severe or complicated malaria

Severe or complicated malaria is a life threatening medical emergency. It may rapidly progress to multi-organ dysfunction and failure. Without prompt and appropriate treatment, it can lead to death. The annual global incidence is estimated to be 350-500m p.a., with *Plasmodium falciparum* (*P. falciparum*) being the predominant causative agent. The disease is responsible, in endemic areas, for 20–45% of hospital admissions and 15–35% of hospital deaths.

About artemether and quinine

- **Artemether** is a well-known potent and rapidly acting blood schizontocide, active against all *Plasmodium* species. It has an unusually broad activity against asexual parasites, killing all stages from young rings to schizonts. In *P. falciparum* malaria, it also kills the gametocytes, including the stage 4 gametocytes.
- **Quinine** is also a well-known potent antimalarial acting principally on the mature trophozoite stage of parasite development. It does not prevent sequestration or further development of circulating ring stages of *P. falciparum* and does not kill the sexual stages of *P. falciparum* mature gametocytes and the pre-erythrocytic stages of malaria parasites. Quinine presents a range of unpleasant side-effects.

About SUDA Ltd

SUDA is an emerging, clinical stage, specialty drug delivery company focused on the development of oral formulations of existing and novel active ingredients addressing a wide range of therapeutic areas.

APPENDIX

Study title:	Phase III, randomised open labelled, active controlled, multi-centre, superiority trial of ArTiMist™ versus intravenous quinine in children with severe or complicated falciparum malaria, or uncomplicated falciparum malaria with gastrointestinal complication
Protocol ID:	ART004
Primary efficacy parameter:	Parasitological success defined as a reduction in parasite count of ≥90% of baseline at 24 hours after first dose
Secondary efficacy parameters:	Complete cure (crude and PCR adjusted); parasite clearance; fever clearance time; early treatment failure; late clinical failure; late parasitological failure; time to return to normal clinical status; no. and incidence of treatment emergent adverse events (TEAEs), serious adverse events, of possible, probable and definite causalities; no. of deaths or neurological sequelae at Day 28.
Pharmacokinetic (PK) objective:	Establishment of the non-compartmental and population PK parameters for ArTiMist™
Centres:	Rwanda (site 001), Ghana (site 004) and Burkina Faso (site 005)
Hospitalisation:	All the patients were treated as hospital in-patients for at least 72 hours after the first dosing. The patients were discharged from hospital on the 4th day at the earliest.
Start date:	16 November 2010
End date:	07 September 2012
ClinicalTrial.gov ID no:	NCT01258049

ART004 - Summary of key data (*not exhaustive*)		
	ArTiMist™	**Quinine Dihydrochloride**
Dosage form	Sub-lingual spray	Solution for IV
Dose	6mg per actuation (100mcl/actuation)	600mg/2mL
No. of randomised subjects	77	74
No. of patients that completed the study	75	72
Withdrawn	2	2
Intention to Treat (ITT)	77	74
Modified (ITT)	70	71
Per Protocol (PP)	68	69
No. of severe or complicated malaria cases	49 (63.6%)	51 (68.9%)
No. of uncomplicated malaria with GI complication	28 (36.4%)	23 (31.1%)
No. of patients with ≥500 *P. falciparum*/mcl	76	74
No. of patients with mixed ≥500 *P. falciparum*/mcl	1	0
Parasitology success (≥90% reduction in parasite count within 24 hours)	**95.6%**	**40.6%**
Early treatment failure	0	10
Late clinical failure	3	1
No. of deaths/neurological sequelae	0	0
No. of treatment-related Serious Adverse Events (SAEs)	0	0
No. of SAEs (incl. rescue therapy)	4	10
No. of SAEs requiring rescue therapy	0	1
No. of patients w/ at least 1 treatment-related TEAE	5	6
No. of patients that reported at least 1 TEAE	43	44
Patients' profile		
Age (Years)	Mean (SD): 2.8	2.5
	Median: 2.7	2.4
	Min & Max: 0.4, 7.1	0.5, 6.0
Male	37	35
Female	40	39
Race: Black African	77	74
Height (cm) of the patients (mean ± SD)	86.98 (±10.65)	86.38 (±10.69)
Weight (kg) of the patients (mean ± SD)	11.70 (± 2.42)	11.21 (± 2.47)
Tympanic temperature (◦C) (mean ± SD)	38.63 (± 1.05)	38.55 (±1.03)