

# ASX Release

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## SUDA LTD ANNOUNCES PEER-REVIEWED PUBLICATIONS OF ARTIMIST™ DATA IN SCIENTIFIC JOURNAL

**PERTH, AUSTRALIA – 24 April 2015:** SUDA LTD (ASX: SUD), a leader in oro-mucosal drug delivery, today announces that two peer-reviewed articles relating to ArTiMist™ have been published in *Antimicrobial Agents and Chemotherapy (AAC)*, which is a journal of the American Society for Microbiology. The AAC is one of the most respected peer-reviewed scientific journals for preclinical and clinical data on novel anti-malarial treatments.

The two articles describe the findings from SUDA's pharmacokinetic (PK) clinical trials of ArTiMist™ and were authored by leading clinicians and PK experts, including Professor Tim Davis, who is Professor at the School of Medicine and Pharmacology, Fremantle Hospital, University of Western Australia. Professor Davis is also the chairman of the Company's Clinical Advisory Board for ArTiMist™.

The first article, which is titled, *'Pharmacokinetics of a novel sublingual spray formulation of the antimalarial drug artemether in healthy adults'*, sets out the results from two PK studies comparing the absorption of the active drug, when delivered with SUDA's sublingual spray (ArTiMist™) versus tablets. The data showed that ArTiMist™ provided greater bioavailability of artemether compared to tablets, and suggested that the majority of artemether delivered by ArTiMist™ is absorbed prior to reaching the gastrointestinal tract (ie: absorbed through the oral mucosal membrane).

The second article is titled, *'Pharmacokinetics of a novel sublingual spray formulation of the antimalarial drug artemether in African children with malaria'*. It describes the PK data from a study of ArTiMist™ in 91 young African children with severe malaria or who could not tolerate oral antimalarial therapy. The absorption pattern in children was consistent with the studies in healthy adults, and multiple dosing with ArTiMist™ was associated with potent antimalarial activity. The authors conclude that ArTiMist™ could be used as a pre-referral treatment for sick children before they are transferred to hospital for definitive management of their malaria.

SUDA's CEO, Mr Stephen Carter, commented: "We are pleased to see these important clinical data published in a prestigious journal for novel antimalarials. The articles further raise the profile of ArTiMist™ with the scientific and medical community and reaffirm its therapeutic advantages in children with malaria. There remains a serious unmet need for

novel antimalarial treatments for children, particularly in the pre-referral setting. The World Health Organisation estimates that in 2013 there were almost 200 million cases of malaria globally with over 0.5 million deaths from the disease.”



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#### **NOTES TO EDITORS:**

##### **About SUDA LTD**

SUDA LTD (ASX: SUD) is a drug delivery company focused on oro-mucosal administration, headquartered in Perth, Western Australia. The Company is developing novel oral spray formulations of existing off-patent pharmaceuticals using its proprietary OroMist® drug delivery technology platform. The many potential benefits of administering drugs through the oral mucosa (ie: cheeks, tongue, gums and palate) include ease of use, lower dosage, reduced side effects and faster response time. SUDA’s product pipeline includes ZolpiMist®, a first-in-class oral spray of zolpidem for insomnia. ZolpiMist® has been approved in the USA and SUDA has rights to the product outside of the Americas and South Africa. SUDA’s most advanced development-stage product, ArTiMist™, is a novel sublingual malaria treatment for children. In a Phase III trial, ArTiMist™ was shown to be superior to intravenous quinine. Other products in development include oral sprays for the treatment of migraine headache, chemotherapy-induced nausea and vomiting, erectile dysfunction and pre-procedural anxiety. For more information, visit [www.sudaltd.com.au](http://www.sudaltd.com.au)

##### **About ArTiMist™**

ArTiMist™ was designed with a child in mind; a child living in a challenging environment where healthcare resources can be very scarce and time is of the essence. ArTiMist™ is the world’s first sub-lingual spray for the treatment of *p. falciparum* paediatric malaria. The active pharmaceutical ingredient in ArTiMist™ is artemether, which is a widely used anti-malarial and is currently administered by infusion or orally in a tablet form. ArTiMist™ is administered sublingually or under the tongue and enters the bloodstream where the parasite lives, attacking at a far greater speed than conventional tablets and reducing the need for continued hospitalisation whilst presenting significant cost savings to governments and relief organisations. ArTiMist™ could be particularly valuable as a pre-referral treatment of sick children before they are transferred to hospitals for definitive management of severe or moderately severe malaria.