

# ASX Release

## SUDA LTD SHAREHOLDER UPDATE

**PERTH, AUSTRALIA – 8 February 2016:** SUDA LTD (ASX: SUD), a leader in oro-mucosal drug delivery, today announces an update to shareholders describing the Company's progress towards its business development goals and advancement of its pipeline of first-in-class oral sprays.

SUDA has started 2016 with real momentum behind its business development activities. The Company is negotiating financial terms with several prospective licensing partners and, in January 2016, received additional requests for term sheets. These negotiations span a number of the Company's oral sprays and a range of territories.

### **ArTiMist™**

The Company's novel anti-malarial sublingual spray continues to attract attention from industry and also funding groups. Two major philanthropic funds have indicated their interest in funding the proposed clinical study to evaluate ArTiMist™ as an early interventional paediatric treatment in the pre-referral setting, before patients are admitted to hospital.

In addition, SUDA has applied for a European grant of Euro 6 million to support the study. The grant proposal received excellent reviews in the first stage of evaluation and has advanced to the second stage of assessment. The reviewers made comments such as: "A successful outcome to this trial could quickly lead to a policy change that would improve disease management." And from another "The impact of ArTiMist™ could be substantial... There is a real need for an effective bridging treatment to sustain severely ill children in remote areas until full treatment can be administered at a referral facility...".

The Company is also in dialogue with the World Health Organization (WHO) with regard to the inclusion of ArTiMist™ in the WHO's Model List of Essential Medicines and their Standard Treatment Guidelines for malaria. This would lead to the provision of ArTiMist™ through the WHO's large-scale procurement of antimalarial medicines for public health use in malaria-endemic countries.

### **SUD-001, SUD-002 and SUD-003**

In 2015, the FDA acknowledged SUDA's proposed development strategy for SUD-001 and requested minor justifications together with a paediatric study plan. The Company has submitted to the FDA the requested information regarding the trial design and is finalising the paediatric study plan. This will provide further clarity on the path to market for prospective licensees in the USA.

Having regained rights to SUD-002 ondansetron oral spray for nausea and vomiting in December 2015, SUDA is working with its regulatory advisors to request a meeting with the FDA. The outcome of this meeting will similarly de-risk the product by setting out the requirements for registration in the US market.

The Company is conducting further studies with its second-generation formulation of SUD-003 sildenafil oral spray for erectile dysfunction. Once SUDA has lodged a new patent application covering its second-generation formulation, the Company aims to publish the data in a peer-reviewed medical journal.

Commenting on SUDA's progress, Mr Stephen Carter, Chief Executive Officer of SUDA said: "We are entering an exciting period for the Company. Our extensive business development activities could lead to a series of licensing deals in 2016 and beyond. In parallel, we are de-risking and adding value to our pipeline of oral sprays. I am delighted by the interest from philanthropic funds in supporting the proposed trial of ArTiMist™ to treat paediatric malaria in the pre-referral setting. Non-dilutive funding for the study would greatly enhance the value of ArTiMist™ as we advance towards a partnership."



**Further information:**

**STEPHEN CARTER**

**CHIEF EXECUTIVE OFFICER / MANAGING DIRECTOR**

**SUDA LTD**

Tel: +61 8 6142 5555

[sjcarter@sudaltd.com.au](mailto:sjcarter@sudaltd.com.au)

**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)