SUDA LTD

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ASX Release

SUDA LTD ANNOUNCES UPDATE ON ARTIMIST™

- Progressing partnering discussions with multiple major pharmaceutical companies
- Revised regulatory strategy to accelerate adoption of ArTiMist™ into the World Health Organisation treatment guidelines
- Support from Medicines for Malaria Venture for new trial of ArTiMist™
- Strategy to publish a series of clinical papers in high profile medical journals

PERTH, AUSTRALIA – 21 August 2014: SUDA LTD (ASX: SUD), a leader in oro-mucosal drug delivery, today announces an update on its antimalarial sublingual spray, ArTiMist™. The Company is on track with its objective to secure a partner for the programme and is working with the World Health Organisation (WHO) and Medicines for Malaria Venture (MMV) to accelerate the inclusion of ArTiMist™ in the WHO's large-scale procurement of antimalarial medicines for public health use.

Following the success of SUDA's business development outreach to the pharmaceutical industry in March and June 2014, the Company has ongoing discussions with multiple prospective partners. These include top-10 major pharmaceutical companies and also mid-sized companies with established antimalarial franchises in malaria-endemic regions. Discussions are at various stages with some companies having completed due diligence and initiated deal negotiations with SUDA.

SUDA has engaged with the WHO in relation to the optimal regulatory strategy that would facilitate the inclusion of ArTiMist™ in the WHO Guidelines for the Treatment of Malaria. The WHO Guidelines are generally adopted by national healthcare agencies in malaria-endemic countries and are used as the basis for large-scale procurement of medicines for public health use.

The WHO has recommended that SUDA firstly seek registration of ArTiMist™ with the US Food and Drug Administration (FDA) or the European Medicines Agency (EMA) under Article 58. Article 58 of Regulation (EC) No 726/2004 allows the EMA's Committee for Medicinal Products for Human Use (CHMP) to give opinions, in co-operation with the WHO, on medicinal products for human use that are intended exclusively for markets outside of the European Union.

In parallel, SUDA has been advised to pursue the WHO Prequalification of Medicines Programme (PQP) for ArTiMist™. Every year, billions of US dollars worth of medicines are purchased by or through international procurement agencies – such as UNICEF, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and UNITAID – for distribution in resource-limited countries. PQP helps to ensure that medicines supplied by procurement

agencies meet acceptable standards of quality, safety and efficacy.

Based on these recommendations, SUDA is targeting US or European registration and WHO Prequalification of ArTiMist™ prior to a regional submission of the Common Technical Document in Africa. The Company is coordinating its strategy with the WHO and MMV and plans to initiate dialogue with the FDA and EMA.

SUDA is making progress with its plan to expand the market of ArTiMist™ from the treatment of severe paediatric malaria to its use as an early interventional treatment when children first show signs of a malaria-like fever, before being referred to hospital. This would represent a significant expansion of the patient population that could benefit from the product and would substantially increase the product's commercial value. It is also an area of unmet medical need with no approved treatments. As a result, it has drawn the attention of the MMV and the WHO.

The MMV is supporting SUDA and the Company's Clinical Advisory Board in the design of a clinical trial of ArTiMist™ in this pre-referral setting. SUDA does not intend to initiate further trials without a partner, but will present the protocol to the WHO and philanthropic funds that have indicated an interest in supporting the clinical evaluation of ArTiMist™ as an early interventional treatment.

SUDA aims to enhance further the profile of ArTiMist™ with a series of peer-reviewed clinical publications in high profile medical journals. Two manuscripts have been drafted and additional papers are planned. The Company is also targeting key medical conferences focused on malaria and tropical diseases at which to present the clinical data.

Commenting on recent developments in relation to the ArTiMist™ programme, Mr Stephen Carter, Chief Executive Officer of SUDA said: "We are making excellent progress towards our goal of securing a pharmaceutical partner for ArTiMist™. The interest in the programme from pharmaceutical companies, and groups like the WHO and Medicines for Malaria Venture, illustrate the drug's potential to change the treatment landscape for paediatric malaria. One senior executive at a major pharmaceutical company described ArTiMist™ as a paradigm shift in the treatment of malaria. We have a clearly defined strategy for adding value to the programme by expanding the use of the product and working with the WHO to accelerate the adoption of ArTiMist™ into their treatment guidelines for malaria."

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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 low-risk oral sprays using novel formulations of existing off-patent pharmaceuticals. 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 most advanced product is a novel sublingual treatment, ArTiMist™, for severe malaria in children. In a Phase III trial, ArTiMist™ was shown to be superior to intravenous quinine. Other development stage products include orals sprays for the treatment of migraine headache, chemotherapy-induced nausea and vomiting and erectile dysfunction. For more information, visit www.sudaltd.com.au

About Medicines for Malaria Venture

Medicines for Malaria Venture (MMV) is a leading product development partnership (PDP) in the field of antimalarial drug research and development working towards the vision of a malaria-free world. Its mission is to reduce the burden of malaria in disease-endemic countries by discovering, developing and facilitating delivery of new, effective and affordable antimalarial drugs. Since its foundation in 1999, MMV has developed and brought to registration four new medicines with partners from over 300 pharmaceutical, academic and endemic-country partners in more than 50 countries. With its partners MMV manages the largest portfolio of antimalarial R&D projects ever assembled, encompassing over 65 projects. MMV is grateful to its donors, including the Bill and Melinda Gates Foundation, the governments of Australia, Ireland, Switzerland, the United Kingdom, the United States of America, Norway and Japan, as well as the Wellcome Trust, the ExxonMobil Foundation and Newcrest Mining Ltd, whose support make this vital work possible.