

ASX Release

SUDA LTD APPOINTS CLINICAL ADVISORY BOARD FOR MALARIA

PERTH, AUSTRALIA – 2 April 2014: SUDA LTD (ASX: SUD), a leader in oromucosal drug delivery, today announces the appointment of four leading malaria experts to its newly founded Clinical Advisory Board. These experts are providing advice and guidance to SUDA on the expansion of the market for ArTiMist™ beyond severe paediatric malaria.

SUDA convened the inaugural meeting of its Clinical Advisory Board on 27 March 2014 to discuss the design of a pivotal Phase III trial of ArTiMist™ as an early interventional treatment in the 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 further clinical evaluation of ArTiMist™.

SUDA's Clinical Advisory Board members are as follows:

- **Professor Tim Davis BMedSc, MB BS, DPhil, FRACP, FRCP** - Professor at the School of Medicine and Pharmacology, Fremantle Hospital, University of Western Australia
- **Professor Ric Price MB (London), MA (Cambridge), BChir (Cambridge)** - Professor of Global Health, the Menzies School of Health Research, Royal Darwin Hospital; and Professor of Tropical Medicine, the Centre of Tropical Medicine, University of Oxford, UK.
- **Professor Kevin Marsh MBChB** - Director of the Kenya Medical Research Institute Wellcome Trust Research Programme, Kenya. Chair of the WHO Malaria Policy Advisory Committee (MPAC).
- **Dr Stephen Rulisa, MD, MMed (Obs/Gyn)** - Head of Obstetrics & Gynaecology, University of Rwanda, School of Medicine; and Principal Investigator for two clinical trials of ArTiMist™, including the successful Phase III trial in children with severe malaria

There is an unmet need for an effective therapy in the pre-referral setting. Severely ill patients with malaria with vomiting, prostration, and altered consciousness cannot be treated orally and need injections. In rural areas, access to health facilities that provide parenteral antimalarial treatment is poor, resulting in effective treatment being delayed until patients reach hospital.

A treatment of ArTiMist™ sublingual spray, prior to referral to hospital, could halt disease

progression by rapidly reducing parasite density. This could then be followed by further doses of ArTiMist™ or other antimalarial treatments, once patients are referred to a hospital or medical centre.

Stephen Carter, CEO of SUDA LTD, commented: “SUDA has assembled a Clinical Advisory Board that brings together leading malaria researchers and clinicians from around the world. These experts are providing valuable advice to SUDA as we seek to expand the opportunity for ArTiMist™ into the pre-referral setting. In parallel, we have initiated commercial discussions with pharmaceutical companies, and we are progressing towards the first marketing application of ArTiMist™ as a treatment for severe paediatric malaria.”

Mr Carter continued: “In malaria-endemic countries, particularly in rural areas, prompt and effective treatment of malaria has proved challenging. Through our discussions with non-governmental groups that fund anti-malarial R&D, there is clear support for evaluating ArTiMist™ in the pre-referral setting and potentially providing a new treatment option for these patients. A fully-funded Phase III trial that expands the market for ArTiMist™ would enhance both the value of the programme and also our negotiating position with prospective partners in the pharmaceutical industry.”



Further information:
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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 sub-lingual treatment, ArTiMist™, for severe malaria in children. Other development stage products include oral sprays for the treatment of migraine headache, chemotherapy-induced nausea and vomiting, and erectile dysfunction. For more information, visit www.sudaltd.com.au

About ArTiMist™

ArTiMist™ is the world’s first sub-lingual spray for the treatment of *p. falciparum* severe 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. The Phase III trial in 150 patients across multiple sites in Africa confirmed that ArTiMist™ was convincingly superior to the current gold standard intravenous quinine treatment. The regulatory dossier is being prepared and will form the basis of applications for marketing approval. SUDA aims to monetize ArTiMist™ through a global partnership or trade sale to the pharmaceutical industry.