

ASX Release

SUDA LTD PRESENTS ARTIMIST™ PHASE III RESULTS AT ASTMH ANNUAL MEETING

PERTH, AUSTRALIA – 6 November 2014: SUDA LTD (ASX: SUD), a leader in oro-mucosal drug delivery, today announces that the Principal Investigator, Dr Stephen Rulisa, from the Phase III trial of ArTiMist™ presented the results at the 63rd Annual Meeting of the American Society of Tropical Medicine and Hygiene (ASTMH) on 5 November 2014 in New Orleans, Louisiana.

The ART004 Phase III trial was a randomised, open-labelled, active-controlled, multi-centre, superiority trial of ArTiMist™ versus intravenous (IV) quinine in 151 children with severe or complicated falciparum malaria, or uncomplicated falciparum malaria with gastrointestinal complications. The results were previously reported in April 2013, but were presented by Dr Rulisa for the first time at the ASTMH Annual Meeting. This event draws together tropical medicine and global health professionals from government, NGOs, philanthropy, the pharmaceutical industry and academia.

Dr Rulisa is the Head of Obstetrics & Gynaecology at the University of Rwanda, Kigali Teaching Hospital in Rwanda, which was one of the sites participating in the study. The data in his presentation demonstrated 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 results showed that 95.6% of the patients treated with ArTiMist™ had their parasite count reduced by $\geq 90\%$ within 24 hours versus 40.6% of the patients treated with IV quinine. Similarly, the secondary efficacy parameters of parasite count reduction and total parasite clearance also showed a statistically significant benefit for ArTiMist™ compared to IV quinine.

Commenting on his presentation at ASTMH, Dr Stephen Rulisa said: “ArTiMist™ has the potential to be an effective anti-malarial 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. I was impressed by the level of interest in ArTiMist™ from key opinion leaders, clinicians and pharmaceutical executives at the ASTMH Annual Meeting.”

Mr Stephen Carter, Chief Executive Officer of SUDA said: “The presentation of the ArTiMist™ Phase III results at the ASTMH Annual Meeting is an important step towards our goals of securing a partner for the asset and also progressing ArTiMist™ towards its adoption into the World Health Organisation’s Standard Treatment Guidelines for large-scale procurement of anti-malarial therapies. The Phase III results provide a compelling argument for the potential use of ArTiMist™ as a treatment for children with malaria.”



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 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 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. SUDA is engaged in dialogue with the World Health Organisation (WHO) and Medicines for Malaria Venture (MMV) to accelerate the inclusion of ArTiMist™ in the WHO’s treatment guidelines and in large-scale procurement of antimalarial medicines for public health use. SUDA aims to monetize ArTiMist™ through a global partnership or trade sale to the pharmaceutical industry.

About ASTMH

The American Society of Tropical Medicine and Hygiene (ASTMH), founded in 1903, is a worldwide organisation of scientists, clinicians and program professionals whose mission is to promote global health through the prevention and control of infectious and other diseases that disproportionately afflict the global poor. Research, health care and education are the central activities of ASTMH members, whose work bridges basic laboratory research to international fieldwork and clinics to countrywide programmes.