SUDA LTD

ACN 090 987 250

ASX Release

SUDA SUBMITS MARKETING AUTHORISATION APPLICATION FOR ARTIMIST®

PERTH, AUSTRALIA – 3 April 2017: SUDA LTD (ASX: SUD), a leader in oro-mucosal drug delivery, today announces that that the Australian Therapeutic Goods Administration (TGA) has accepted for review the Marketing Authorisation Application (MAA) for ArTiMist® (artemether sublingual spray) for the treatment of children with severe malaria.

In late 2016, SUDA made a pre-submission to the TGA and based on that filing the TGA has advised that the filing is complete and deemed the MAA submission to be effective and has accepted the dossier for evaluation. The TGA now has 255 days to complete its review and provide an opinion, including potential approval of the ArTiMist Marketing Authorisation.

The MAA for ArTiMist includes data from the ART004 Phase III pivotal trial in 150 paediatric patients with severe complicated malaria or uncomplicated malaria with gastro-intestinal complications. The randomised study demonstrated the superiority of ArTiMist in reducing parasite count compared to standard-of-care intravenous quinine.

SUDA is continuing discussions with parties in relation to a trade sale or partnering agreement as part of the product commercialisation strategy.

In parallel with this, SUDA has commenced pre-planning for a product launch. This has included negotiations around manufacture and supply chain logistics, pricing models and distribution channels. A number of parties with a distribution footprint and extensive experience in Africa have expressed interest in entering into distribution arrangements with SUDA.

Mr Stephen Carter, SUDA's CEO and Managing Director, commented: "Based on the positive results from our clinical studies in paediatric patients and our discussions with the World Health Organisation and other groups, we believe that pursuing a marketing authorisation in Australia will accelerate access to ArTiMist for patients in malaria-endemic countries. The acceptance of this filing brings us one step closer to addressing the unmet medical need of severe malaria. It is a debilitating condition that can cause long-term neurological problems and death. Children under five years of age are one of most vulnerable groups affected by severe malaria because they lack immunity to the parasite."

Further information:
STEPHEN CARTER
CHIEF EXECUTIVE OFFICER / MANAGING DIRECTOR
SUDA LTD
Tel: +61 8 6142 5555
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 low-risk oral sprays using its OroMist® technology to reformulate existing pharmaceuticals. The many potential benefits of administering drugs through the oral mucosa (i.e.: 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™ is marketed in the USA and SUDA has rights to the product outside of North America. 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

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.