SUDA PHARMACEUTICALS LTD

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ASX Release

SUDA EXPANDS DIALOGUE WITH WORLD HEALTH ORGANISATION FOR ARTIMIST®

PERTH, AUSTRALIA – 7 May 2018: SUDA Pharmaceuticals Ltd (ASX: SUD), a leader in oro-mucosal drug delivery, today announced that it intends to meet with the World Health Organisation (WHO) to discuss the addition of ArTiMist® (artemether sublingual spray) to the WHO's Guidelines for the treatment of children with severe malaria.

The decision to meet with the WHO prior to the anticipated regulatory approval of ArTiMist by the Australian Therapeutic Goods Administration in late 2018 was stimulated by SUDA's discussions with a prospective acquirer/licensee of the product. As part of the negotiation, the pharmaceutical company is seeking to know whether any further data is required by the WHO prior to adopting ArTiMist into the Guidelines.

According to the WHO, mortality from untreated severe malaria (particularly cerebral malaria) approaches 100%. With prompt, effective antimalarial treatment and supportive care, the rate falls to 10–20% overall.

Death from severe malaria often occurs within hours of admission to a hospital or clinic, so it is essential that therapeutic concentrations of a highly effective antimalarial drug be achieved as soon as possible.

The current WHO Guidelines recommend prompt parenteral (ie: injectable) or rectal anti-malarial treatment. Two classes of medicine are available for parenteral treatment of severe malaria: artemisinin derivatives (artesunate or artemether) and the cinchona alkaloids (quinine and quinidine). In the Phase III trial of ArTiMist, SUDA's sublingual spray of artemether was shown to be superior to intravenous quinine, one of the commonly used treatment options for severe malaria.

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NOTES TO EDITORS:

About SUDA Pharmaceuticals Ltd

SUDA Pharmaceuticals 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 the US and Canada. SUDA has submitted a Marketing Authorisation Application to the Australian Therapeutic Goods Administration for ArTiMist®, its 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, PAH, epileptic seizures and pre-procedural anxiety. For more information, visit www.sudapharma.com

About ArTiMist®

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. SUDA submitted a Marketing Authorisation Application for ArTiMist to the Australian Therapeutic Goods Administration in April 2017.