

ASX Release

ArTiMist Regulatory Update

PERTH, AUSTRALIA – 18th April 2019: SUDA Pharmaceuticals Ltd (ASX: SUD), a leader in oro-mucosal drug delivery, has received a preliminary notice of denial for marketing approval of its ArTiMist[®] oral spray. The preliminary notice comes as a result of a process to obtain approval to market the ArTiMist[®] oral spray in Australia. The process was commenced nearly 24 months ago during which neither SUDA nor its regulatory advisors received any indication that the process would not be successful.

The preliminary notice was provided to SUDA as a copy of the resolution of the Advisory Committee of Medicines (ACM), which provides independent medical and scientific advice to the Minister for Health and the Therapeutic Goods Administration. SUDA's regulatory advisors have explained that whilst the resolution has been received, it does not form part of the TGA's milestones for the evaluation of prescription medicines, and we will still need to wait for the official Delegate's letter before we can assess the decision in detail and determine the next steps. The letter is expected in mid-May.

Upon receipt of the Delegate's letter, SUDA, in consultation with our advisors, will review the reasons for the decision and will determine the appropriate actions to be taken. SUDA has been informed that there is a process that will allow SUDA to appeal the decision.

SUDA's CEO, Mr Stephen Carter, commented: "We are very surprised by the decision of the ACM, especially as the various TGA reviewers had all recommended the product for approval. We still believe that ArTiMist has a role in the global fight against malaria and SUDA will now take time to review the reasons for the ACM decision and determine the actions to be taken."



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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. 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; and cancer.

For more information, visit www.sudapharma.com