SUDA PHARMACEUTICALS LTD

ACN 090 987 250

ASX Release

ArTiMist Appeal Reasons for Decision

PERTH, AUSTRALIA – 4 October 2019: Further to our announcement released on the 1st October, SUDA Pharmaceuticals Ltd (ASX: SUD), a leader in oro-mucosal drug delivery, provides a summary of the reasons for the decision from the delegate of the Minister regarding its appeal requesting reconsideration of the initial decision of the delegate of the Secretary.

During the review process, the three key sections of the application covering the Pre-clinical, Clinical and Chemistry Manufacturing and Control aspects of the application were reviewed in detail.

These sections cover the quality, safety and efficacy of the proposed drug product. All sections were reviewed by the appropriate sections within the TGA and each sectional reviewer, based on the information provided and reviewed, recommended the product for approval.

The outcome of the appeal was that the Ministers Delegate upheld the original decision to deny the approval of ArTiMist.

The reason for the decision was stated as: “that the Delegate was not satisfied that the safety and efficacy of the product had been satisfactorily established for the purpose for which it is intended for use.”

A key recurring reason that appears throughout the decision document is that the Delegate had concerns with regard the use of an artemisinin monotherapy and the potential of misuse or abuse that may result in the formation of artemisinin resistance. The Delegate believes that this results in “an overall negative benefit to risk profile for ArTiMist.”

The Delegate was further concerned that due to the low level of adherence to current treatment guidelines in malarial endemic areas, the ease of use of ArTiMist and the number of doses in a vial could lead to further non-compliance to treatment guidelines that may result in the occurrence of further resistance.

SUDA had proposed an education program for healthcare workers to overcome this problem but the Delegate was concerned as to the success of the program because of the reported lack of adherence to treatment guidelines.

Further information:
Paul Hopper
Executive Chairman
SUDA Pharmaceuticals Ltd
Tel: +61 (0) 406 671 515
phopper@sudapharma.com

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