

# ASX Release

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## ArTiMist Appeal Lodged with TGA

**PERTH, AUSTRALIA – 9 August 2019:** SUDA Pharmaceuticals Ltd (ASX: SUD), a leader in oro-mucosal drug delivery, has lodged its appeal with the Australian Therapeutic Goods Administration (TGA) against the notice of denial for marketing approval of its ArTiMist® oral spray.

SUDA lodged its request for reconsideration Under Section 60 of the *Therapeutic Goods Act 1989* with the TGA on Wednesday 7<sup>th</sup> August and received acknowledgement of receipt of the application from the TGA on the 8<sup>th</sup> of August.

In accordance with section 60(4) of the Act, the decision upon reconsideration must be notified to SUDA in writing within sixty days from the date of receipt by the Minister. As our notification was received by the Minister on 7 August 2019, the decision upon reconsideration by the Minister's delegate is therefore due by (latest), Friday, 4 October 2019.

As stated in SUDA's market update dated 18<sup>th</sup> July 2019: "Based on discussions with our advisors and experts in the field of malaria, SUDA has decided that it has strong grounds for an appeal under Section 60 of the Therapeutic Goods Act of 1989". Upon compilation of the appeal document we continue to hold this view.



**Further information:**  
**STEPHEN CARTER**  
**CHIEF EXECUTIVE OFFICER / MANAGING DIRECTOR**  
**SUDA Pharmaceuticals Ltd**  
Tel: +61 8 6142 555  
[sjcarter@sudapharma.com](mailto:sjcarter@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. SUDA is also fully licensed to purchase and manufacture cannabinoid products. For more information, visit [www.sudapharma.com](http://www.sudapharma.com)