

ASX Release

ArTiMist Regulatory Update

PERTH, AUSTRALIA – 18 July 2019: SUDA Pharmaceuticals Ltd (ASX: SUD), a leader in oro-mucosal drug delivery, provides an update to the ArTiMist® regulatory update released 18 April 2019.

On the 14th May, SUDA received the official Delegate's letter which did not differ materially from the preliminary notice of denial for marketing approval of its ArTiMist® oral spray. As advised in the 18 April announcement, SUDA has continued consultation with industry experts and our regulatory advisors to determine the appropriate actions to take.

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* and is currently preparing its submission. We have approached relevant industry professionals and regulatory consultants in Australia and overseas that have been involved in the ArTiMist program and its clinical trials, as well as receiving input and advice from members of our Science Advisory Board with experience in malaria. This information has been forwarded to our regulatory experts who will collate the responses into the appeal document.

The final date for submitting the appeal is 14th August 2019. It is envisaged that SUDA will lodge prior to this date. Upon receipt of the Appeal, the Minister has 60 days to reply to the Appellant.

Whilst SUDA are confident in our arguments and are hopeful of a successful outcome of the appeal, it should be noted that, if for any reason SUDA is not satisfied with the outcome of the Section 60 appeal, there are several further avenues that we can consider including making an application to the Administrative Appeals Tribunal (AAT) for review. Applications to the AAT must be made within 28 calendar days of the Minister's decision regarding a Section 60 appeal. Further to this secondary avenue of appeal, and since the AAT provides only a merit review process, affected parties may appeal at any time to the Federal Court on the grounds of the legality of a decision.



Further information:
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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