ACN 090 987 250

# ASX Release

## SUDA Pharmaceuticals achieves TGA GMP licence

- **SUDA is granted licence to manufacture therapeutic goods from Australia's TGA**
- **Licence includes chemical and physical pharmaceutical testing and release for supply**
- **Licence covers non-sterile solutions, sprays and pharmaceutical starting materials.**

**PERTH, AUSTRALIA – 21 AUGUST 2018:** SUDA Pharmaceuticals Ltd (ASX: SUD), a leader in oro-mucosal drug delivery, is pleased to announce that it has been awarded a licence to manufacture therapeutic goods (GMP Licence) from the Australian Therapeutic Goods Administration, Australia's peak pharmaceutical regulatory authority. The GMP Licence allows SUDA to carry out testing and release for supply of therapeutic goods within the licenced categories of non-sterile solutions, sprays and Active Pharmaceutical Ingredients (API's)

The licence is internationally recognised and in conjunction with SUDA's ISO 9001:2015 accreditation, confirms that SUDA is working to the world's most stringent pharmaceutical standards. The GMP Licence provides further commercial opportunities for the company allowing it to carry out activities for itself and its partners that would have previously needed to have been contracted to a third party.

SUDA's Executive Chairman said that "the GMP Licence is the result of 4 years work and adds a significant commercial advantage to the company for its Formulation Laboratory. The achievement of a GMP Licence is a significant milestone for any pharmaceutical company and will provide an advantage to our BD team in their negotiations."

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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. ZolpiMist is partnered with Eddingpharm in China and Teva Pharmaceuticals in Latin America. 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