

ASX Release

SUDA LTD FILES PATENT APPLICATION FOR NOVEL MUCOSAL PENETRATION TECHNOLOGY

PERTH, AUSTRALIA – 2 November 2016: SUDA LTD (ASX: SUD), a leader in oro-mucosal drug delivery, today announced that it has filed a provisional patent application with IP Australia for a novel mucosal penetration drug delivery technology. The application was filed under the international Patent Cooperation Treaty (PCT), which enables SUDA to seek patent protection for its technology in more than 145 countries.

The technical field of the provisional patent application is entitled: *'A method for modifying the penetration of active agents through mucosal membranes using hydrotopes.'* It is based on positive results from *ex-vivo* and *in-vivo* studies evaluating SUDA's new-generation formulation of SUD-003 sildenafil oral spray for erectile dysfunction, together with *in-vitro* data investigating the technology with a broad range of other molecular drug classes.

The recent *in-vivo* study with SUDA's new-generation formulation of SUD-003, using the novel technology, showed a significant improvement in bioavailability (quantity of drug absorbed) compared to the Company's original formulation. SUDA is conducting further studies with SUD-003 and anticipates meeting with the FDA to discuss the clinical strategy in CY 2017.

The penetration-enhancing technology is intended to overcome some of the challenges associated with delivery of therapeutic drugs across the oro-mucosal membrane. SUDA's new technology has been shown to increase significantly the efficiency and quantity of drug that crosses the membrane and reaches the blood system.

SUDA's novel technology opens up new possibilities for oro-mucosal administration of therapeutic drugs. Furthermore, by avoiding the gastrointestinal tract and first-pass metabolism, SUDA's drug delivery platform not only allows for efficient and convenient dosing but may reduce the side-effects associated with traditional tablets.

SUDA's CEO, Mr Stephen Carter, commented: "We are delighted that our R&D efforts have culminated in the filing of this patent application. Our new penetration-enhancing technology is a breakthrough for oro-mucosal drug delivery and has broad applications across different molecular classes.

"Whilst we recognise that a patent filing may not necessarily result in a granted patent, we can now start commercialising the technology with prospective partners and re-engaging with pharmaceutical companies interested in our novel SUD-003 oral spray for erectile dysfunction. I look forward to presenting the exciting data on our new penetration-enhancing technology at the Annual Symposium of Drug Delivery Systems on 16 November 2016."



Further information:

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NOTES TO EDITORS:

About SUDA LTD

SUDA 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 (ie: 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 North America. SUDA's most advanced development-stage product, ArTiMist®, is a 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 and pre-procedural anxiety. For more information, visit www.sudaltd.com.au