

ASX Release

SUDA GRANTED US PATENT FOR SUD-002 ORAL SPRAY TO TREAT NAUSEA & VOMITING

PERTH, AUSTRALIA – 27 July 2015: SUDA LTD (ASX: SUD) (SUDA), a leader in oro-mucosal drug delivery, is pleased to announce that it has received a Notice of Grant from the US Patent Office for patent application 13/445,331 entitled “Buccal, Polar and Non-Polar Spray Containing Ondansetron”. The patent number is US 9,078,816.

The patent provides broad protection in the world’s largest pharmaceutical market for SUDA’s first-in-class oral spray formulation of ondansetron to treat nausea and vomiting induced by chemotherapy, radiotherapy and also in post-operative settings. The patent has been granted or is pending in other major jurisdictions.

Clinical studies have successfully demonstrated that the Company’s SUD-002 8mg spray is statistically bioequivalent to the commercially available 8mg ondansetron tablet. It is well tolerated and can be conveniently administered in multiple doses. In addition, SUD-002 delivered statistically faster absorption versus the tablet as defined by median time to detectable drug levels of ondansetron. SUDA is working with its US partner for SUD-002 to prepare for a meeting with the FDA to discuss the programme.

Mr Stephen J Carter, CEO commented: “We are delighted to have been granted this US patent covering our SUD-002 ondansetron spray for the treatment of nausea and vomiting in cancer and post-operative settings. This further validates our OroMist® technology platform and our position as a leading company in the field of oro-mucosal drug delivery. We look forward to advancing SUD-002 towards a New Drug Application in the USA with our partner, Amherst Pharmaceuticals.”



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 novel formulations of existing off-patent 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 the Americas and South Africa. 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

About SUD-002

SUD-002 is a first-in-class mint-flavoured oral spray formulation of ondansetron (marketed in tablet form by GlaxoSmithKline under the brand name of Zofran®), prescribed for the treatment of induced nausea and vomiting in cancer therapy and in post-operative settings. It has been designed to provide patients with a rapid onset of action, convenience, and it is a desirable alternative to patients requiring antiemetic therapy who have difficulty in swallowing. The product has been evaluated in over 300 patients in multiple clinical trials. The studies successfully demonstrated that SUD-002 8mg dose was statistically bioequivalent to the current commercially available 8mg ondansetron tablet; it was well tolerated and conveniently administered in multiple doses. In addition, SUD-002 delivered statistically faster absorption as defined by median time to detectable drug levels of ondansetron at 15 minutes versus 30 minutes for the tablet.