

ASX Release

SUDA GRANTED FIRST PATENT FOR ORAL SPRAY OF SILDENAFIL IN AUSTRALIA

- The first patent covering SUDA's SUD-003 first-in-class oral spray formulation of sildenafil (active ingredient in Viagra®) has been granted in Australia
- This patent is pending in other major jurisdictions
- A proof-of-concept study of SUD-003 demonstrated efficient absorption of sildenafil across the oral mucosa with superior bioavailability compared to Viagra® tablets
- SUDA is progressing partnership discussions and plans to meet with the FDA in 2015 to discuss the development plan for SUD-003

PERTH, AUSTRALIA – 30th January 2015: SUDA LTD (ASX: SUD), a leader in oro-mucosal drug delivery, is pleased to announce that it has received a Notice of Grant from the Australian Patent Office for patent application 2011/264941 entitled "oral spray formulations and methods of administration of sildenafil".

This is the first patent to be granted covering SUDA's first-in-class SUD-003 oral spray of sildenafil for the treatment of erectile dysfunction. The patent extends until 2031 and is pending in other major jurisdictions.

An initial proof-of-concept study of SUD-003 showed efficient absorption of sildenafil into the blood with enhanced bioavailability. Hence, SUD-003 requires less of the active drug to achieve the same therapeutic effect as the commercially available Viagra® tablets.

SUDA is completing the development of a second-generation formulation of SUD-003, which includes flavouring, taste masking and optimal permeation characteristics that are designed to enhance further the onset of action and bioavailability. The Company is progressing discussions with prospective pharmaceutical partners in several major territories. In addition, the Company plans to meet with the US FDA in 2015 to discuss the company's development plan, which is intended to provide the data required to achieve registration of SUD-003.

Mr Stephen J Carter, CEO commented: "We are delighted to have been granted the first patent covering our oral spray delivery of sildenafil for erectile dysfunction. This further validates our OroMist technology platform and our position as a leading company in the field of oro-mucosal drug delivery. The grant of this patent will further strengthen our negotiating position with prospective partners in the pharmaceutical industry."

Mr Carter continued: "In the US alone, erectile dysfunction affects >18m individuals. Pfizer reported \$1.9 billion of Viagra® sales in 2013. Our second-generation SUD-003 oral spray formulation is designed to achieve quicker onset of action, improved bioavailability and enhanced patient convenience compared to Viagra® tablets. Hence, we believe the market opportunity for SUD-003 is substantial."



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-003

SUD-003 is a first-in-class oral spray formulation of sildenafil citrate (marketed in tablet form by Pfizer, Inc. under the brand name of Viagra®) for the treatment of erectile dysfunction. It has been designed to provide patients with a rapid onset of action, convenience, reduced food effect and lower dose. Pilot studies with the first-generation formulation have demonstrated that 20mg dose (2 sprays) was equivalent to Viagra® 25mg tablet with respect of systemic exposure. Furthermore, SUD-003 demonstrated an excellent safety profile and was well tolerated. The second-generation formulation has been enhanced with flavouring, taste masking and optimal permeation characteristics to further accelerate the onset of action. Erectile dysfunction is a highly prevalent condition among men. Its incidence, prevalence and severity are associated with aging, comorbidities and lifestyle choices. The erectile dysfunction market continues to grow with US sales >US\$2.9bn in 2012.