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SUDA LTD

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# ASX Release

## SUDA LTD ENTERS INTO LICENCE AND COLLABORATION AGREEMENT WITH AMHERST

- SUDA grants an exclusive licence to SUD-002 oral spray for Americas and South Africa
- SUDA receives an exclusive global licence (excl. Americas and South Africa) to Zolpimist® oral spray
- Zolpimist® is a patented, fast-acting sedative for insomnia, registered in the USA
- Amherst to fund all further development of SUD-002 in the USA

**PERTH, AUSTRALIA – 8 January 2015:** SUDA LTD (ASX: SUD) (**SUDA**), a leader in oro-mucosal drug delivery, and Amherst Pharmaceuticals (**Amherst**), a US specialty pharmaceutical company based in New Jersey, have entered into a cross-licence and collaboration agreement to develop and commercialise SUDA's oral spray of ondansetron (**SUD-002**) for the treatment of nausea and vomiting induced by chemotherapy or radiotherapy, and Amherst's oral spray of zolpidem tartrate (**Zolpimist®**) for insomnia.

Under the terms of the agreement, SUDA is granting Amherst an exclusive licence to manufacture, develop and commercialise SUD-002 in the Americas, being North America and South America, and also South Africa. SUDA receives an exclusive licence to manufacture, develop and commercialise Zolpimist® in all territories excluding the Americas and South Africa. Both parties have the right to sub-license in their respective territories. SUDA is entitled to a 6 to 12 per cent share of income from Amherst's commercialisation of SUD-002 in the Americas and South Africa. Similarly, Amherst will receive a 6 to 12 per cent share of income from SUDA's commercialisation of Zolpimist® in SUDA's respective territories.

**Zolpimist®**

Zolpimist® is a novel cherry-flavoured oral spray designed to provide patients with a faster onset of sleep, as demonstrated in multiple clinical trials. This fast-acting sedative was approved by the FDA in December 2008 and is being commercialised in the USA. Zolpidem tartrate, the active ingredient in Zolpimist®, is marketed by Sanofi in tablet form as Stilnox® or Ambien®. Zolpidem tartrate is the most widely prescribed sleep aid on the market with a market share in excess of 70%. The global insomnia therapeutic market is forecast to reach US$2.1bn in 2017.

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Mr Stephen Carter, CEO of SUDA, commented on gaining licensing rights to Zolpimist®: "Zolpimist® is a truly differentiated product in the insomnia market with a unique oro-mucosal delivery technology that offers patients clear advantages. We believe Zolpimist® will be the treatment of choice for patients with insomnia and we are excited to have secured a licence outside of the Americas and South Africa. Zolpimist® is the first marketed product in our portfolio of oral sprays and it represents a substantial value proposition for SUDA. We have already received unsolicited approaches from potential licensees of Zolpimist® in our territories and we are planning an extensive business development initiative around the product in 2015."

Amherst will provide SUDA with the approved US regulatory dossier for Zolpimist®, which can be used for marketing applications in Europe and other countries that have similar legislation in relation to drug reformulations. Marketing applications may be submitted within 12 months. SUDA will commence a business development initiative in 2015, designed to secure pharmaceutical partners rapidly for Zolpimist® in its territories.

**SUD-002**

Amherst will be responsible for any further development work that is required to obtain marketing approval of SUD-002 in the USA. SUDA is entitled to use the clinical data generated by Amherst and the US regulatory dossier to support marketing applications for SUD-002 in other countries. Hence, Amherst's investment in the development and registration of SUD0-002 in the USA will enhance SUDA's objective to out-license SUD-002 in other regions of the world.

"This agreement with Amherst marks an important milestone for SUDA. It provides validation of our strategy and of SUD-002's market potential as well as strengthening our pipeline of oral sprays with a marketed product for insomnia," said SUDA's Mr Carter. "Amherst is a strong partner whose management and advisory team are highly experienced in the development and commercialisation of products within the Americas and South Africa."

Mr Daniel D'Agostino, CFO of Amherst Pharmaceuticals, said: "We are excited to add SUD-002 to our pipeline. Both SUD-002 and Zolpimist® were developed with the same patented oro-mucosal delivery technology and both products offer advantages to patients through quicker onset of action and convenience of administration without the need to swallow. We look forward to working with SUDA on the successful registration and commercialisation of both products across the world."

**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

| Product | Active Ingredient | Pre-clinical | Clinical | Marketing Approval | Mkt Size | Partnerships (Incl. territories) |
|---|---|---|---|---|---|---|
| *ZolpiMist® | Zolpidem | Insomnia | | | $2.1bn | |
| ArtiMist™ | Artemether | Malaria | | | >$500m | |
| SUD-001 | Sumatriptan | Migraine headache | | | $3.2bn | |
| SUD-002 | Ondansetron | CRINV** and PONV*** | | | $2.5bn | • Amherst (Americas & ZA)<br>• Kwang Dong (Korea) |
| SUD-003 DuroMist™ | Sildenafil | Erectile dysfunction | | | $4.1bn | |
| SUD-004 | Sildenafil | Pulmonary arterial hypertension | | | $2.7bn | |
| SUD-005 | Midazolam | Pre-procedural anxiety | | | $170m | |

**About Amherst Pharmaceuticals**

Amherst Pharmaceuticals is a specialty pharmaceutical company, headquartered in New Jersey, USA, principally focused on launching high-value, FDA-approved products into the market. Amherst Pharmaceuticals is commercialising Zolpimist® by positioning it as the alternative to oral zolpidem tablets with a clear and differentiable mode of action based on its unique characteristics. The key strategic objectives of Amherst Pharmaceuticals are to introduce Zolpimist® as a leader in the insomnia market and to launch Ondansetron Oral Spray as the preferred anti-emetic.

**About SUD-002**

SUD-002 is a first-in-class, patented, bioequivalent and taste-masked oro-mucosal spray formulation of ondansetron, a first-generation 5-HT3 inhibitor, originally marketed by GlaxoSmithKline in tablet form under the brand name of Zofran®. It is the most commonly prescribed anti-emetic to treat cancer therapy and post-operative induced nausea and vomiting. Each metered actuation (one spray) of SUD-002 delivers 4mg of ondansetron succinate in 100µl of fluid. The dispensing device contains 20 actuations. The global anti-emetic market is forecast to reach US$3.6bn in 2015 from US$2.5bn in 2010.

**About Zolpimist®**

ZolpiMist® is a fast-acting sedative, prescribed for the treatment of insomnia, approved and commercialised in the USA. It is a novel cherry-flavoured bioequivalent oro-mucosal spray formulation of zolpidem tartrate, originally marketed by Sanofi in tablet form under the brand name of Stilnox® or Ambien®. Each metered actuation (one spray) of ZolpiMist® delivers 5mg of zolpidem tartrate in 100µl of fluid. The dispensing device is child-resistant containing 60 actuations. The global insomnia therapeutic market is forecast to reach US$2.1bn (GBI Research Report) in 2017 with the US being the largest market. Zolpidem tartrate is the most widely prescribed sleep aid on the market with a market share in excess of 70% in 2013 according to IMS data.