

# ASX Release

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## **SUDA LTD TAKES MAJOR STEP FORWARD WITH ARTIMIST™**

- **New agreement expands SUDA's rights to ArTiMist™ anti-malarial treatment**
- **SUDA-controlled Australian entity will own global rights to ArTiMist™ for the entire field of malaria**
- **No ongoing royalty obligation to ProtoPharma**
- **New structure enhances the value of the asset and sets the foundation for securing a global partnership**
- **SUDA and ProtoPharma will pool expertise to fast track commercialisation**

**PERTH, AUSTRALIA - 12 November 2013:** SUDA LTD (ASX: SUD), a leader in oromucosal drug delivery, and UK-based ProtoPharma Ltd today announced a new agreement to restructure the commercial terms of the ArTiMist™ anti-malarial Project. This is a key element required to allow the Project to be commercialised.

Formed in 2006, the original agreement provided SUDA with a license to ArTiMist™ in Africa, India, Asia and the Pacific region for the treatment of malaria primarily in children, subject to SUDA funding the clinical development. There was also a royalty obligation on product sales payable to ProtoPharma.

SUDA and ProtoPharma believe that the new agreement enhances the value of the ArTiMist™ asset and sets the foundation for a global partnership with a pharmaceutical company.

Under the new agreement with ProtoPharma, all of the intellectual property and global rights in relation to ArTiMist™ will be owned by a newly incorporated Australian company, Malaria Research Company Pty Ltd (MRC). SUDA will control the new entity and will own 80% of MRC, with ProtoPharma owning the balance. There will be no royalty obligations to ProtoPharma, and the worldwide territorial rights to ArTiMist™ for the entire field of malaria will be consolidated into MRC.

SUDA will manage MRC, and both SUDA and ProtoPharma will use their joint resources and expertise to take the project through to a commercial outcome.

The parties are currently working together to finalise the Common Technical Document (CTD). This comprehensive report will form the basis of regulatory submissions for

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marketing approval and will be central to the due diligence pack offered to prospective pharmaceutical partners. The first regulatory submission is expected to be lodged by mid CY2014. In parallel, SUDA in consultation with its advisor, Torrey Insights, will initiate discussions with parties interested in collaborating to commercialise ArTiMist™.

“We are delighted to have restructured our relationship with ProtoPharma for ArTiMist™, giving SUDA greater control and broader commercial rights over our lead development product,” noted Stephen Carter, Chairman and Chief Executive Officer of SUDA LTD. “We believe that the new structure of ownership is an excellent outcome for our shareholders and ensures that the ArTiMist™ asset is well positioned for a global partnership or a trade sale to the pharmaceutical industry. We look forward to working closely with ProtoPharma on the commercialisation of the Project.”



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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 most advanced product is a novel sub-lingual treatment, ArTiMist™, for severe malaria in children. In a Phase III trial, ArTiMist™ was shown to be superior to intravenous quinine. Other development stage products include oral sprays for the treatment of migraine headache, erectile dysfunction and chemotherapy-induced nausea and vomiting.

##### **About ArTiMist™**

ArTiMist™ is the world's first sub-lingual spray for the treatment of *p. falciparum* severe paediatric malaria. The active pharmaceutical ingredient in ArTiMist™ is artemether, which is a widely used anti-malarial and is currently administered by infusion or orally in a tablet form. The ART004 Phase III trial in 150 patients across multiple sites in Africa confirmed that ArTiMist™ was convincingly superior to the current gold standard intravenous quinine treatment. The regulatory dossier is being prepared and will form the basis of applications for marketing approval. SUDA aims to monetize ArTiMist™ through a global partnership or trade sale to the pharmaceutical industry.

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