

ASX Release

SUDA COMPLETES ACQUISITION OF NOVEL ORO-MUCOSAL ANTI-CANCER AGENT

PERTH, AUSTRALIA – 24 January 2018: SUDA Pharmaceuticals Ltd (ASX: SUD), a leader in oro-mucosal drug delivery, announced today that it has completed the acquisition of the global intellectual property relating to anagrelide, an anti-thrombotic agent, that has recently shown promise as a novel anti-cancer agent.

SUDA plans to formulate an oro-mucosal spray of anagrelide utilising the Company's OroMist® technology, which could potentially avoid the side-effects associated with the molecule when administered as an oral capsule.

Under the terms of the acquisition agreement with UK-based Aluztra Bio Ltd, the relevant global patents covering anagrelide have been assigned to SUDA. Aluztra and its partners will be entitled to a low single-digit percentage royalty on direct net sales or a share of income generated by SUDA from commercialisation of an oro-mucosal spray of anagrelide. No other payments have been made or are due.

Anagrelide is currently used as an anti-thrombotic agent to reduce elevated levels of platelets. It is recognised that platelets play an important role in the growth and metastatic spread of tumours. The recent American Society of Hematology Annual Meeting, which is the most widely attended event in the field, included data from several key opinion leaders, who presented on the underlying mechanisms by which the platelet-tumour interaction is mediated and how the reduction of platelets can help prevent tumour growth and metastasis.

Anagrelide has the potential to be developed as an effective anti-cancer agent but is fundamentally limited in its current formulation by cardio-stimulatory side-effects. An oro-mucosal spray formulation of anagrelide could minimise these side-effects by avoiding first-pass generation of a highly potent cardio-excitatory metabolite of the drug in the liver.

The global market for cancer drugs has grown to more than \$100 billion in annual sales. Newer cancer treatments include immunotherapies that stimulate the patient's own immune system.

Anagrelide would be complementary to such treatments by reducing the platelet numbers thereby reducing the proliferative and protective effect that platelets exhibit on metastatic cells and further rendering circulating cancer cells more susceptible to attack by the body's own killer cells. Thus, it potentially offers a novel and valuable first-in-class treatment option for cancer.

Mr Stephen Carter, SUDA's CEO and Managing Director, commented: "We are delighted to have finalised the acquisition of anagrelide. We are developing an oral spray formulation using our proprietary OroMist® technology that enables the active drug to be efficiently absorbed across the oral mucosa membrane. This could provide a compelling new strategy for the treatment of solid tumours. There is substantial data in the literature and recently presented at the American Society Hematology Annual Meeting to support the theory that non-enteral administration of anagrelide could avoid the dose-limiting cardio-toxicity associated with first-pass metabolism of this novel anti-cancer agent."



Further information:

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NOTES TO EDITORS:

About SUDA Pharmaceuticals Ltd

SUDA Pharmaceuticals 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 (i.e.: 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 US and Canada. SUDA has submitted a Marketing Authorisation Application to the Australian Therapeutic Goods Administration for ArTiMist®, its 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, PAH, epileptic seizures and pre-procedural anxiety. For more information, visit www.sudapharma.com

About blood platelets in cancer

Cancer survival across all solid tumour types has been shown to be related to the number of blood platelets a patient has, cells which are more usually associated with the clotting process. However, platelets are now known to provide essential growth factors that nourish cancer cells and enable them to take hold and develop into tumours. Hence, those patients with the highest platelet numbers are least likely to survive. This has been shown across a wide range of solid tumours including cancer of the brain, oral cavity, the head and neck, thyroid carcinoma, gastrointestinal cancers, pancreatic, hepatocellular cancer, colorectal cancer, cancer of the lungs and bronchus, cancer of the ovaries, endometrium, cervix, breast, prostate, kidneys, skin mesothelioma, melanoma and gallbladder.

About Anagrelide

The pharmacology of anagrelide enables the selective lowering of platelet numbers without significantly affecting clotting or the formation of other blood cell lines and, in this respect, is unique. Currently anagrelide is only available as a solid oral formulation and is used exclusively as an anti-thrombotic agent. The drug's fundamental limitation which precludes its use in the treatment of cancer is its cardio-stimulatory side-effect profile. These effects are known to be due to a highly potent cardio-excitatory metabolite of the drug, formed in large quantities during its initial passage through the liver after oral administration. The use of proprietary non-enteral formulation such as an oro-mucosal spray would minimise this first pass effect in the liver.