SUDA PHARMACEUTICALS LTD

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# ASX Release

# SUDA Licenses a Novel iNKT Cell Therapy Platform from Imperial College London

- **SUDA obtains a global, exclusive Licence from Imperial College London for a novel invariant Natural Killer T (iNKT) cell therapy platform for cancer treatment.**
- **The iNKT cell platform can be used in conjunction with multiple chimeric antigen receptors (CARs) to target blood cancers.**
- **iNKT cells are expected to be suitable for off-the-shelf dosing, as one healthy donor can supply cells to treat many patients.**
- **CAR-iNKT cells have been shown to outperform conventional CAR-T cell therapies in preclinical studies.**
- **SUDA intends to raise a minimum of $3m through a Placement to sophisticated investors.**

**PERTH, AUSTRALIA – 18 June 2021:** SUDA Pharmaceuticals Ltd (ASX: SUD), today announces that it has signed a global, exclusive Licence Agreement with Imperial College London for a novel invariant Natural Killer T (iNKT) cell therapy platform. SUDA's new iNKT cell therapy platform, currently in the preclinical stages and developed by Professor Anastasios Karadimitris at Imperial College London, has been under development for several years. The iNKT cell therapy platform can be used in conjunction with chimeric antigen receptors (CARs) to treat various blood cancers.

Cellular therapies that harness the immune system to treat cancer have ushered in an exciting era in the battle against cancer, with several products resulting in a complete cure for some patients. Still, a limitation for currently approved products is that the cell therapy must be manufactured from a patient's own cells, making the process cumbersome and costly.

**Research at Imperial**

The technology developed at Imperial by Professor Karadimitris focuses on a specific immune cell type, iNKT cells, and his research group was the first to demonstrate that they

are protective against graft versus host disease (GVHD). This provides a critical advantage that the **iNKT cell platform may be used off-the-shelf**, meaning that the cells can be isolated from a healthy donor, modified to enhance their activity against cancer and stored frozen, ready to be administered to cancer patients as needed.

The natural properties of iNKT cells are expected to reduce the complexity of delivering the cell therapy to cancer patients and help to reduce the costs of such an important treatment modality. This has the potential to solve one of the industry's significant challenges: manufacturing the therapeutic from each individual's own cells.

Research from the laboratory of Professor Karadimitris was recently published in the prestigious journal Cancer Cell, one of the leading journals for cancer research (https://www.sciencedaily.com/releases/2018/10/181009102535.htm).

The work demonstrates that the natural properties of iNKT cells allow them to target cancer cells. iNKT cells can be further modified to arm them with a CAR, and CAR-iNKT cells have two ways to recognise, attach to, and destroy cancer cells making them dual targeting. In preclinical studies, CAR-iNKT cells have shown superior activity relative to conventional cell therapies in eradicating cancer cells and extending tumour-free survival. CAR19-iNKT cells are being developed for the treatment of CD19 expressing cancers, including non-Hodgkin's lymphoma.

The technology platform has long patent life, expected to expire in 2038 and has entered national phase in Europe, China, Canada, Australia and the US.

SUDA CEO and MD, Dr. Michael Baker, said "Cell therapies have transformed the way we think about cancer treatment. The iNKT cell therapy platform provides an opportunity to target several cancers using a product that we expect to have superior activity and to be more cost-effective, which should allow the therapy to reach more individuals."

"SUDA will be the only ASX listed CAR-iNKT cell therapy company that is working on this cellular platform and we look forward to progressing the technology into clinical trials." he added.

**Imperial College London**

Imperial College London is consistently ranked as one of the best universities in the world and its Faculty of Medicine, alongside its partners, enables Imperial's continuous evolution as an international powerhouse of medical education, research and innovation.

"Imperial College London is delighted to license this technology to SUDA Pharmaceuticals," said Stephanie Morris, Imperial's Director of Industry Partnerships and Commercialisation, Medicine.

"We are impressed with the ability of their executive team to push and bring therapies to market expeditiously. At Imperial, our mission is to deliver world-class, transformative

scientific research for societal impact. We believe SUDA has the vision to offer innovative therapies to cancer patients."

**Key Terms of The Licence Agreement**

The terms of the licensing agreement are non-dilutive for SUDA shareholders with no immediate material financial impact on the Company as a result of signing the agreement.

The licensing payments include an upfront fee, annual maintenance fees and for the first oncology product developed, there are industry standard, non-dilutionary development milestones for initiating Phase 1, Phase 2 and Phase 3 clinical trials and for receipt of regulatory approval of the product in major territories. The Licence also includes commercial milestones based on achieving sales targets and a single digit royalty on future sales, and sublicensing fees.

The Licence Agreement will expire upon the last to expire patent (or any other relevant patent extension term) or ten years from commercial launch, whichever is longer. There are no associated termination fees.

In addition to the Licence Agreement, SUDA soon also expects to enter into a Collaborative Research Agreement with Imperial College London, facilitating further research to expand the platform and develop additional intellectual property.

**SUDA's Role in the Oncology Market**

The Licence Agreement involving the iNKT cell therapy platform adds substantially to SUDA's existing exposure to the oncology market. The Company gained a foothold in the oncology space in 2017 via its acquisition of the exclusive, worldwide patents for the molecule anagrelide, a therapy under development to reduce high platelet levels in cancer patients, which are associated with poor prognosis.

SUDA continues to progress the development of anagrelide, having recently contracted the services of MedPharm who have been involved with the development of 55 approved products. Furthermore, Dr Anil K. Sood and Professor Gunnar Birgegård both recently joined SUDA's scientific advisory board to provide expertise for the development of anagrelide to treat metastatic disease.

**About Cellular Therapy to Treat Cancer**

Cellular therapy is an innovative type of cancer treatment that utilises human immune cells to fight the disease. The immune cells may be activated, expanded and delivered back to patients or genetically modified, expanded and delivered back to patients. The genetic modification provides the cells with the ability to make a CAR that will target a specific marker on the cancer cell, allowing the immune cells to attach to and eliminate the cancer cells. To date, the majority of research for cellular therapies has focused on T cells and Natural Killer (NK) cells. The technology developed at Imperial College London focuses on a different cell type called invariant Natural Killer T (iNKT) cells, which provide two key

advantages; they already contain a receptor that targets cancer cells, and they are expected to be capable of being dosed off-the shelf.

Cell therapy is already a commercially relevant and powerful therapeutic modality for the treatment of cancer. The first U.S. Food and Drug Administration-approved CAR-T cell products, Kymriah and Yescarta (Novartis and Gilead products, respectively), treat leukemia and lymphoma. More recently, Tecartus (Kite/Gilead), Breyanzi (Bristol Myers Squibb) and Abecma (Bristol Myers Squibb) received FDA approval to treat mantle cell lymphoma, large B cell lymphoma and multiple myeloma, respectively.

To date, cellular therapies have had success in blood cancers, but only with cell therapies that rely on the use of the patient's own cells. A primary unmet goal remains, which is to develop a product capable of being dosed off-the-shelf, which may be resolved by the iNKT cell platform.

**Placement**

In conjunction with the Licence, the Company anticipates raising a minimum of $3m via an institutional placement to be conducted through Baker Young to support the initial development of the iNKT cell therapy, including hiring key personnel and initiating the manufacturing of critical components to produce the product. Further details of the capital raising will be announced shortly.

For further information about the proposed Licence Agreement with Imperial College London, please refer to SUDA's website https://sudapharma.com/.

For and on behalf of the Board and for further information please contact:

**Dr Michael Baker**

**Chief Executive Officer & Managing Director**

**SUDA Pharmaceuticals Ltd**

Tel: +61 (0) 403 468 187

**NOTES TO EDITORS:**

**About SUDA Pharmaceuticals Ltd**

SUDA Pharmaceuticals Ltd (ASX: SUD) is a drug delivery company focused on treating oncology and diseases that affect the central nervous system, 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 tartrate for the treatment of short-term insomnia. ZolpiMist is approved by the TGA and is marketed in the USA. SUDA has rights to the product outside of the US and Canada. Other products in development include oral sprays for the treatment of migraine headache, motion sickness, drug resistant epilepsy and certain cancers.

For more information, visit www.sudapharma.com

**About Imperial College London**

Imperial College London is one of the world's leading universities. The College's 20,000 students and 8,000 staff are working to solve the biggest challenges in science, medicine, engineering and business.

Imperial is the world's fifth most international university, according to Times Higher Education, with academic ties to more than 150 countries. Reuters named the College as the UK's most innovative university because of its exceptional entrepreneurial culture and ties to industry.

Imperial staff, students and alumni are working round-the-clock to combat COVID-19. Imperial has nearly two thousand key workers, and is at the forefront of coronavirus epidemiology, virology, vaccine development and diagnostics. More than one thousand Imperial staff and students are volunteering to support the NHS.

http://www.imperial.ac.uk/

This announcement contains certain statements which may constitute forward-looking statements or information (''forward-looking statements"), including statements regarding negotiations with third parties and regulatory approvals. These forward-looking statements are based on certain key expectations and assumptions, including assumptions regarding actions of third parties and financial terms. These factors and assumptions are based upon currently available information and the forward-looking statements contained herein speak only as of the date hereof. Although the expectations and assumptions reflected in the forward-looking statements are reasonable in the view of the Company's directors and management, reliance should not be placed on such statements as there is no assurance that they will prove correct. This is because forward-looking statements are subject to known and unknown risks, uncertainties and other factors that could influence actual results or events and cause actual results or events to differ materially from those stated, anticipated or implied in the forward-looking statements. These risks include, but are not limited to: uncertainties and other factors that are beyond the control of the Company; global economic conditions; risk associated with foreign currencies; and risk associated with securities market volatility. The Company assumes no obligation to update any forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements, except as required by Australian securities laws and ASX Listing Rules.