



Non-deal Roadshow

September 2021

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SUDA Pharmaceuticals *Vision and Mission*

SUDA Pharmaceuticals is a biotechnology company focused on the development of treatments for its two focus areas; cancer and conditions that affect the central nervous system

Vision

- SUDA Pharmaceuticals aspires to be a world-leading biotechnology company helping people live longer and healthier lives

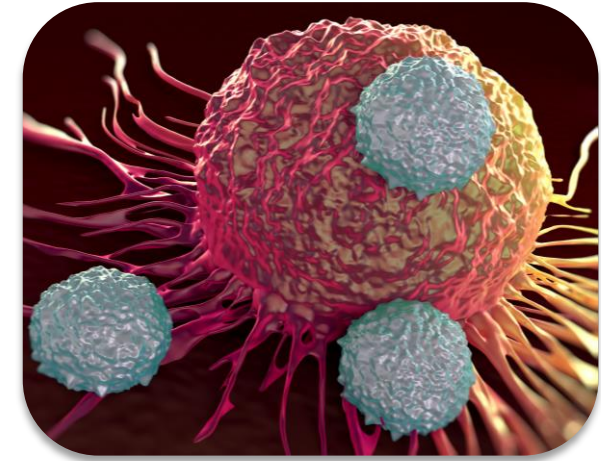
Mission

- SUDA will develop its existing products and look to acquire additional platforms it believes will have an impact on the treatment of cancer and conditions affecting the central nervous system

Values

- We are patient centric
- We are data driven
- We strive for excellence
- We are innovative
- We are milestone focused
- We never give up
- We are accountable
- We act with honesty and integrity

Oncology



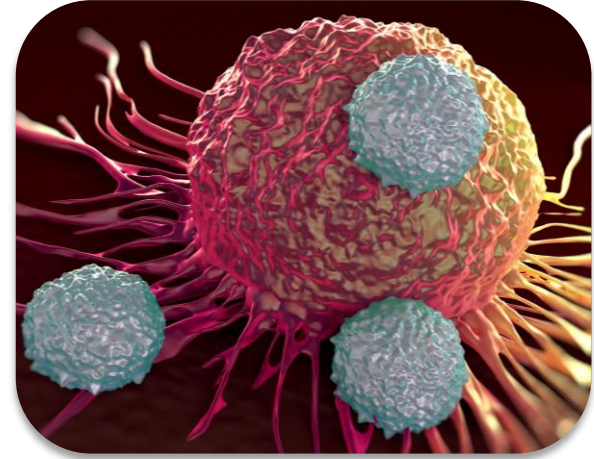
Central Nervous System



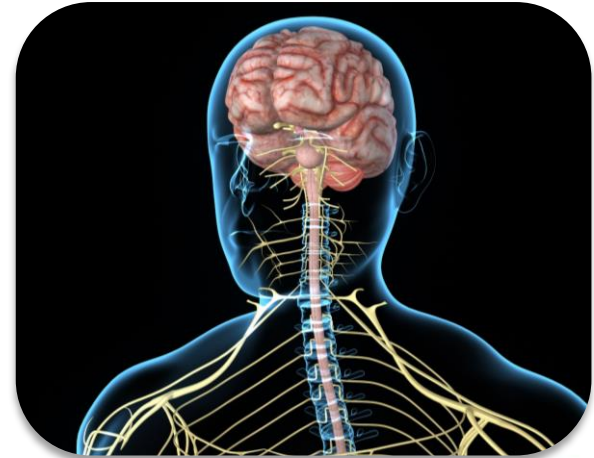
Company Highlights

- **Recent Acquisition of a Novel iNKT Cell Therapy Platform:** SUDA secured a global licence to a novel invariant natural killer T (iNKT) cell therapy platform from Imperial College London. It is initially being developed for the treatment of blood cancers
- **Developing Anagrelide for the Treatment of Cancer:** SUDA holds the only patents for use of anagrelide for the treatment of metastatic disease. We anticipate the oral spray to be a safer product for the treatment of cancer
- **Secured an Australian Partner to Commercialise ZolpiMist® for the Treatment of Insomnia:** ZolpiMist received TGA approval in July 2020 for the treatment of short-term insomnia. SUDA signed an agreement with the multinational pharmaceutical company, STADA, for Australia with an option for New Zealand.
- **Unique Platform Technology – OroMist™:** Reformulate existing billion-dollar drugs for oral spray delivery, which may create a faster path to market and cost and time savings

Oncology



Central Nervous System



Company Overview

Financial Snapshot

ASX CODE	SUD
Market capitalisation*	\$27 million
Shares on issue	480.82 million
52-week low / high	\$0.033 / \$0.075
Cash (30 June 2021)	\$6.7 million
Sector	Biotechnology

Major Shareholders

Shareholder	Ownership (%)*
ZERRIN INVESTMENTS PTY LTD	18,400,000 (3.83%)
UBS NOMINEES PTY LTD	15,064,640 (3.13%)
KAMALA HOLDINGS PTY LTD	11,500,000 (2.39%)
CHELSEA INVESTMENTS (WA) PTY LTD	10,000,000 (2.08%)
SCINTILLA STRATEGIC INVESTMENTS LIMITED	6,500,000 (1.35%)

* as of Sep 6, 2021

Senior Leadership Team



Chairman

Paul Hopper

Over 25 years experience in the medical, healthcare & life sciences sectors. Focussed on start-up and rapid growth companies, he has served as either Founder, Chairman, non-executive director or CEO, of more than fourteen companies in the US, Australia and Asia.

Mr Hopper has founded, or technology seeded, six companies on the ASX and Nasdaq.



CEO and MD

Dr. Michael Baker

Over 15 years experience in scientific research, drug development and venture investing sectors. He was an Investment Manager with the leading Australian life science fund, BioScience Managers. He also conducted due diligence to shortlist investment opportunities and played an active role in managing portfolio companies.



Executive Director

David Phillips

Senior Business Development Executive with over 35 years in the healthcare industry. Including 23 years in GSK, 12 years in Biotech and as Managing Partner of SR One (GlaxoSmithKline's Corporate Venture Fund). During this period Mr Phillips was a member of the investment committee reviewing greater than 30 deals. David has been responsible for over 50 Pharma/Biotech deals and 10 M&A transactions.



Director

David Simmonds

David was a senior audit partner with Ernst & Young from 1989 to 2017. From 2008 to 2013, David led the Capital Markets desk in Australia with responsibility for overseeing or reviewing all Australian cross border fundraisings. David was a member of the Board of MS Research Australia.



Director

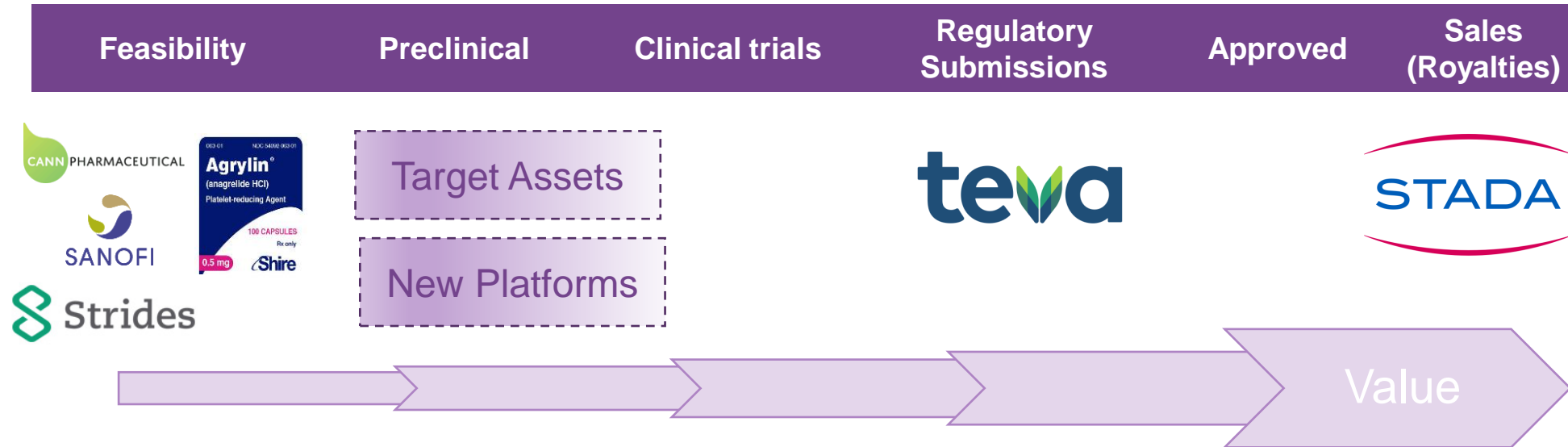
Dr. Debora Barton

Over 20 years of oncology experience, in academia, as a practicing physician and in the biotechnology/pharmaceutical industry. Served in key senior executive positions, including Carisma Therapeutics where Dr Barton is currently the Chief Medical Officer, Iovance Biotherapeutics and Advanced Accelerator Applications, acquired by Novartis during Debora's tenure.



SUDA's Focus For 2021

- ZolpiMist commercialization (Teva, STADA, other territories)
- Integrate and develop new technologies – iNKT Cell Therapy Platform
- Identify and acquire new platform technologies
- Anagrelide formulation stabilisation
- Early-stage feasibility development work



ZolpiMist[®] - Insomnia

- ZolpiMist is SUDA's spray version of the insomnia drug Ambien/Stilnox, Sanofi's blockbuster
- Short-term insomnia has an estimated prevalence of 9.5% in the US¹
- Sleep problems rose from 16% to **25%** during the COVID-19 pandemic (University of Southampton)
- STADA to commercialise SUDA's TGA approved ZolpiMist in Australia (upfront payments and a double-digit royalty)
- Current Licensee populations:
 - Teva: ~350 million
 - STADA: ~25 million
 - Discussions with additional territories are underway
- SUDA to supply finished product

teva

STADA



SUDA
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1. <https://www.ajmc.com/view/insomnia-overview-epidemiology-pathophysiology-diagnosis-and-monitoring-and-nonpharmacologic-therapy>
2. <https://www.southampton.ac.uk/news/2020/08/sleeploss-lockdown.page>

ZolpiMist is SUDA's first Commercialisation Deal

Why STADA?

- STADA Arzneimittel is a global pharmaceutical company headquartered in Germany
- STADA sells its products in 120 countries
- STADA employs more than 12,300 people worldwide
- Greater than €3 billion in group revenue

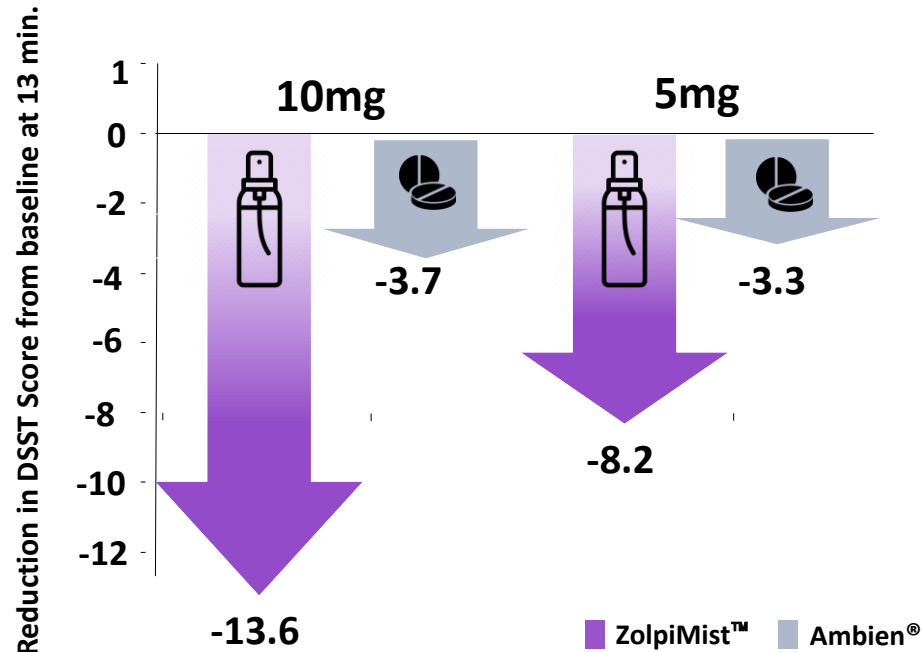


Key terms of the Agreement:

- SUDA will receive an upfront fee of \$170,000 plus a milestone payment of \$40,000
- SUDA will receive a 10% royalty based on net sales of the enhanced product
- STADA has the option to distribute the product in New Zealand
- The Agreement is a perpetual, exclusive Licence for ZolpiMist for Australia
- The milestone payment is linked to the approval of the enhanced child resistant lock
- SUDA to coordinate manufacture and supply the product at agreed supply prices

ZolpiMist – Sleep Response

ZolpiMist™ induced sleepiness significantly faster than Ambien®



DSST = Digit Symbol Substitution Test

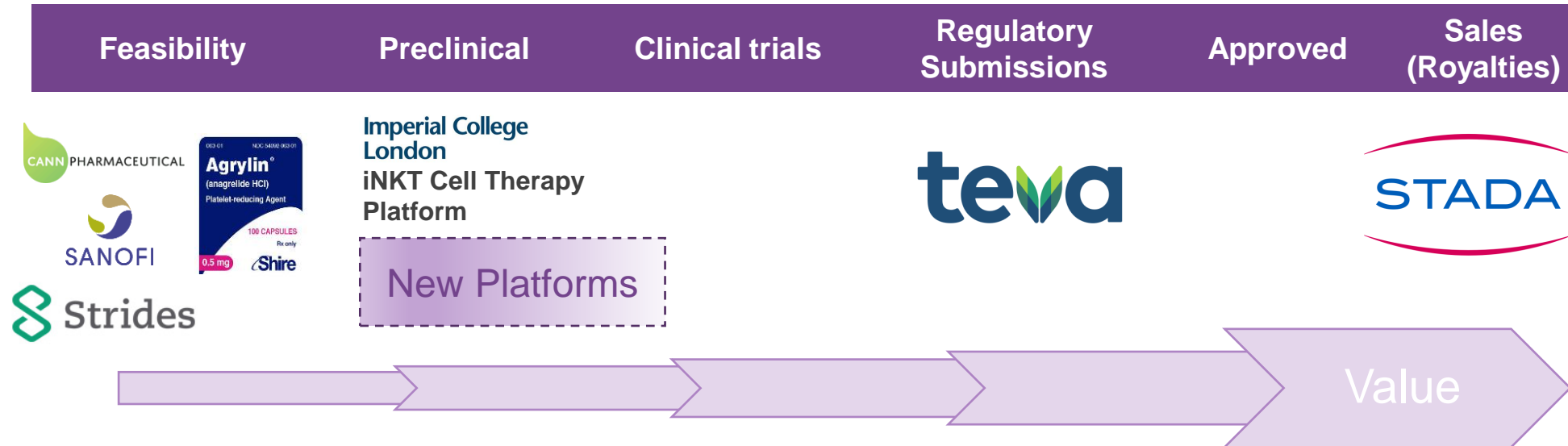
PD Endpoint - Changes in the DSST scores from baseline measurement to 13 and 23 minutes post-dosing



ZolpiMist™ demonstrated significantly faster onset of sedation compared to Ambien® tablets

SUDA's Focus For 2021

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iNKT cell therapy – Acquired June 2021 (key highlights)

SUDA's **i**nvariant **N**atural **K**iller **T** (iNKT) cell therapy platform is at the forefront of immuno-oncology drug development

Pre-clinical studies show that:

- CAR-iNKT cells work **more efficiently** than conventional cell therapies
- CAR-iNKT cells outperform CAR-T cells, **rapidly clearing** the cancer cells and **increasing the number of surviving animals** by 1.5x when the CD1d protein is on the surface of cancer cells
- CAR-iNKT cells cause a **secondary remission** without additional treatment

In addition:

- CAR-iNKT cells provides dual-targeting to kill cancer cells
- The platform has “off-the-shelf” potential where one source can treat multiple patients
- Initial drug development will focus on haematological malignancies (blood cancers)

The Inventor – Imperial College London, UK



**Imperial College
London**

Hugh and Josseline Langmuir

**CENTRE FOR
MYELOMA RESEARCH**

Imperial College London:

- Consistently ranked one of the top 10 universities in the world
- Voted 10th most innovative university by Reuters¹
- Since its foundation, application of its work to industry, commerce and healthcare is central to its mission
- The Imperial Clinical Research Facility, based alongside the Hammersmith Hospital, supports investigator led clinical trials up to Phase 2a
- Imperial's Centre for Advanced Therapeutic Medicinal Products (ATMPs; including cell therapies) aims to increase the cohesion and critical mass of teams within the College to catalyse translation of promising new ATMP treatments

Professor Anastasios Karadimitris is the inventor and investigator that has driven the research

- He has spent decades researching immune cells and their impact in cancer.
- He performed his research training with:
 - Professor Lucio Luzzatto at Memorial Sloan Kettering Cancer Centre, New York, USA,
 - Professor Irene Roberts at Hammersmith Hospital, London
 - Professor Vincenzo Cerundolo at the Weatherall Institute for Molecular Medicine, Oxford.
- He is Chair and Director of the Hugh and Josseline Langmuir Centre for Myeloma Research
- In April, he assumed the role of co-Director of the Centre for Haematology, Imperial College London
- Professor Karadimitris is the chair of SUDAs Scientific Advisory Board

1. <https://www.reuters.com/innovative-universities-2019>

Natural killer

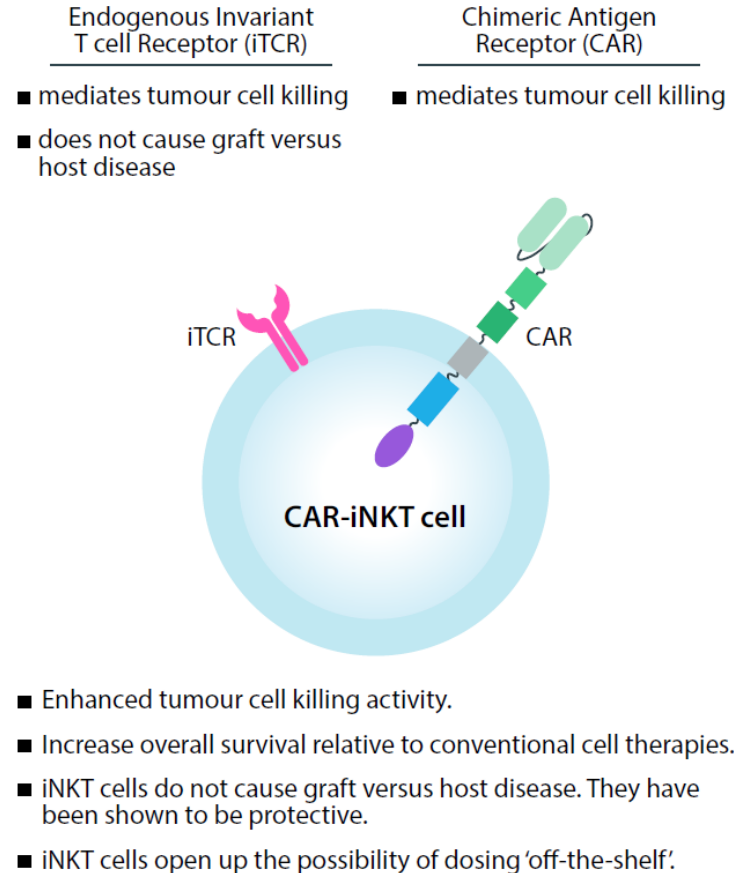
A cell therapy that harnesses one of the body's rarest immune cells – the natural killer T cell – could transform the treatment of blood cancers and other diseases.

By David Silverman for Imperial Enterprise

CAR-iNKT Platform Highlights

- Chimeric Antigen Receptor (CAR) invariant Natural Killer (iNKT) cell therapy – CAR-iNKT – has been developed for the treatment of cancer
- iNKT cells naturally target cancer cells and by introducing a CAR, they are dual targeting and have enhanced activity over conventional CAR-T cells
- The iNKT cell T Cell Receptor (TCR) does not change between people and iNKT cells are protective against graft versus host disease
- iNKT cells can be administered “off-the-shelf” and clinical use validates their safety profile
- iNKT cells could be engineered to express multiple CARs to maximise destruction of cancer cells
- CAR-iNKT cells can be used to target multiple cancer types, including blood cancers and solid tumours
- The licence from Imperial College London is an exclusive, global licence for use of the iNKT cell therapy platform to treat human disease

CAR-iNKT cell therapy

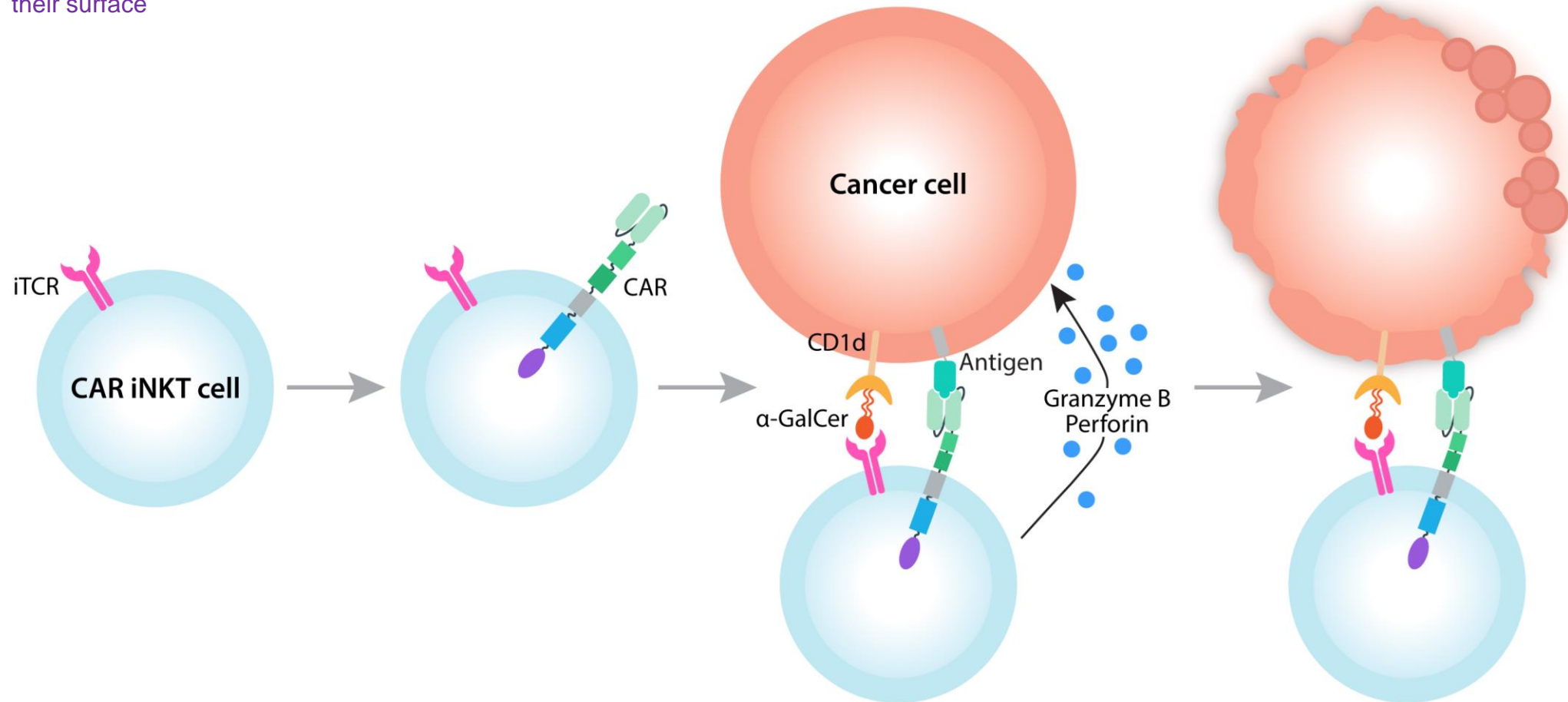


Additional CARs

- CD19
 - Bristol Myers Squibb™
 - NOVARTIS PHARMACEUTICALS
 - GILEAD
- BCMA
 - Bristol Myers Squibb™
- CD20
- CD22
- CD79b
- CD123
- Others....

How does the CAR-iNKT Cell Platform Work?

1. iNKT cells contain an iTCR that naturally assists to recognise and kill cancer cells that have CD1d on their surface
2. We introduce a chimeric antigen receptor (CAR) to target cancer cells, making them dual targeting
3. CAR-iNKT cells are activated after they attach to the cancer cells, releasing components to trigger cancer cell death
4. The cancer cell is killed



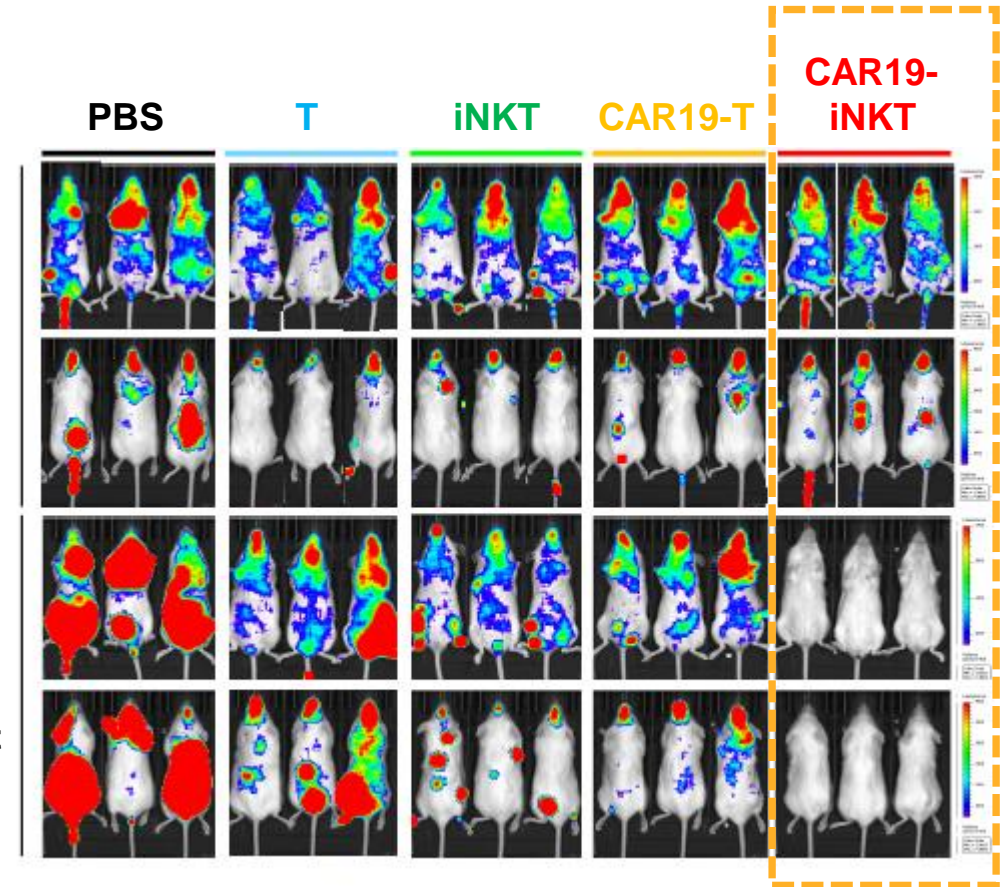
CAR19-iNKT Cells: Enhanced Tumour Killing *In Vivo*

In vivo anti-tumour activity of CAR19-iNKT after three days

- Tumour cells expressing CD1d were intravenously delivered into mice
- Mice were treated with:
 - Nothing (PBS)
 - Unmodified T cells (T)
 - Unmodified iNKT cells (iNKT)
 - CAR19-T cells
 - CAR19-iNKT cells
- After three days, all cancer cells in the iNKT treated mice were eradicated
- Cancer cells persisted with all other treatments
- CAR19-iNKT cells display swift action and memory-like effect

Day 0

3 Days after treatment

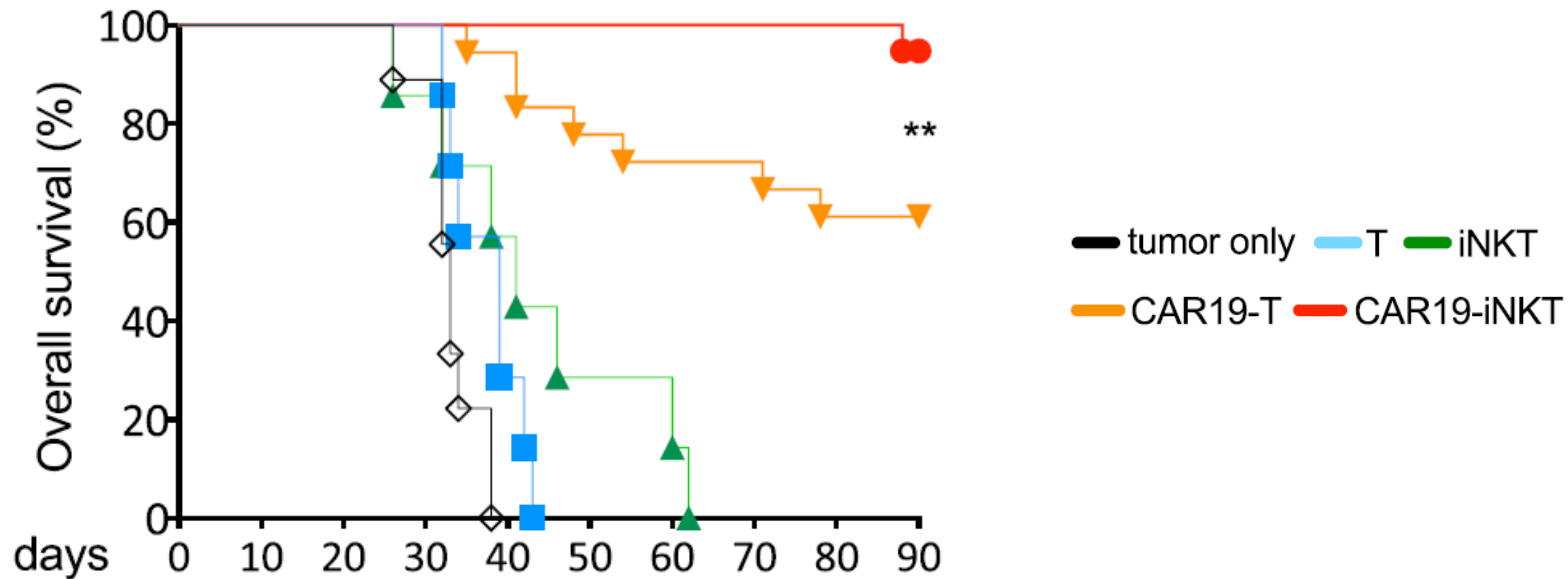


Rotolo *et al.*, Cancer Cell (2018)

CAR19-iNKT Cells: Superior Animal Survival

In vivo anti-tumour activity of CAR19-iNKT cells

- Tumour cells expressing CD1d were intravenously delivered into mice
- Mice were treated with, Nothing (tumour only), Unmodified T cells (T) Unmodified iNKT cells (iNKT) CAR19 T cells or CAR19-iNKT cells
- After 90 days only mice treated with CAR19-T cells or CAR19-iNKT remained alive
- 1.5x more mice treated with CAR19-iNKT cells remained alive after 90 days relative to CAR19-T cells

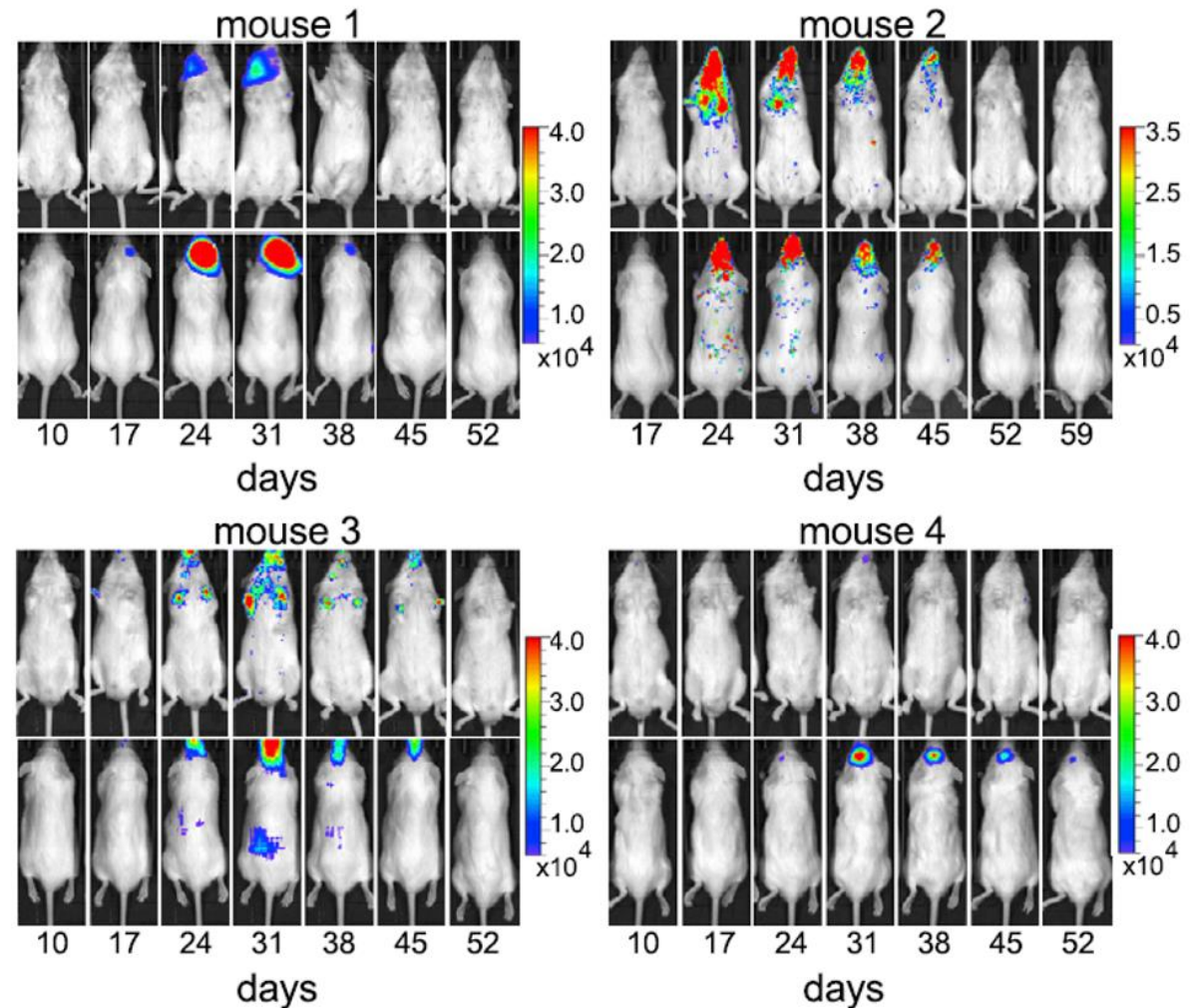


Rotolo *et al.*, Cancer Cell (2018)

CAR19-iNKT Cells Demonstrate Spontaneous Remission

In vivo anti-tumour activity of CAR19-iNKT cells following relapse

- Tumour cells expressing CD1d were intravenously delivered into mice
- Four mice treated with CAR19-iNKT cells had the cancer return to the brain
- In all four mice, the cancer was eliminated a second time with no additional dosing
- This provides evidence that CAR19-iNKT cells can survive and continue to protect against cancer cells *in vivo*



Rotolo *et al.*, Cancer Cell (2018)

The Benefits of “Off-the-shelf” Cell Therapy

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Traditional CAR-T cell therapy manufacturing processes are complicated and expensive, requiring every patient's immune cells to be collected, frozen, genetically modified, expanded to sufficient numbers and frozen again for shipment back to the hospital for patient dosing



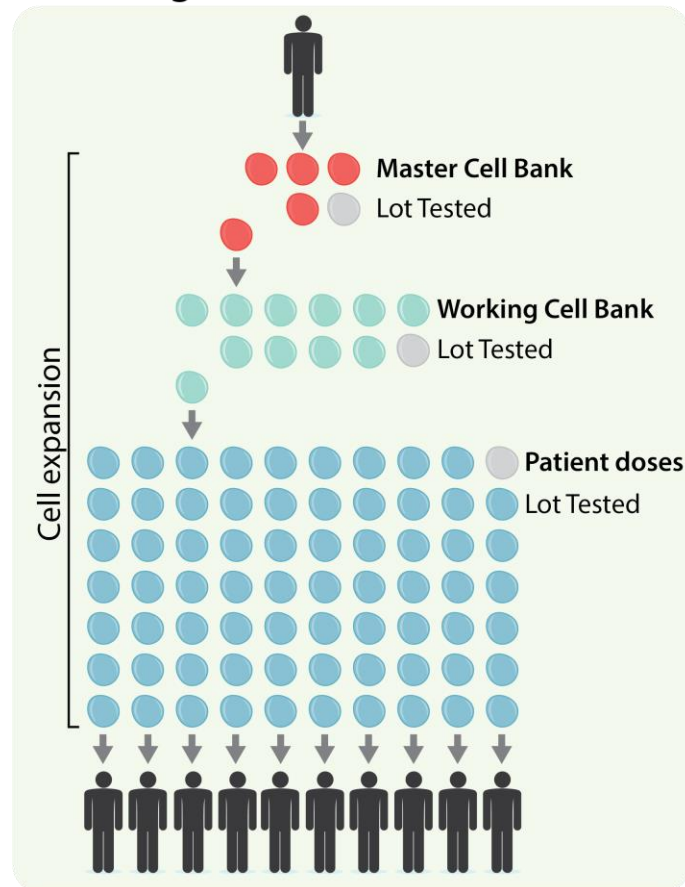
‘Off-the-shelf’ dosing will enable the drug to reach more patients faster as the product will be produced from a healthy donor and stored to be used when required. This means patients will not need to wait and are not at risk of their condition worsening during the therapy production phase



Starting from healthy donor cells is likely to yield a better product with superior activity against cancer cells as the immune cells from a patient may have been subjected to the ravages of cancer cells and chemotherapy reducing the quality of the starting material, so they may not be as effective

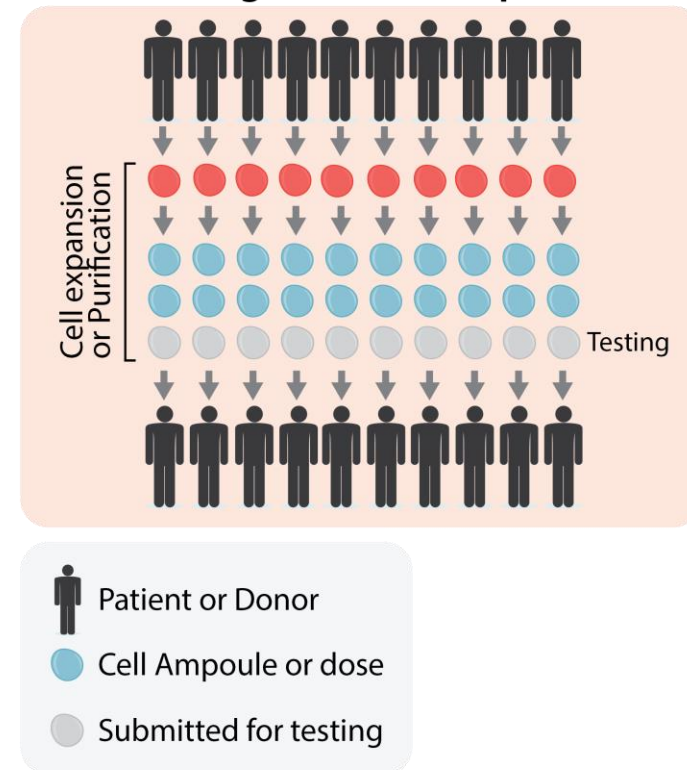
SUDA's technology

Allogeneic/Universal Donor



Current technology

Autologous/Patient Specific



Recent Commercial Activity for Cell Therapy Platforms

Cell Type	Company	Date	Deal Type	Total Value (US\$)
iNKT	 APPIA BIO	August 2021	Collaboration	875m
T and Natural Killer	 CARIBOU BIOSCIENCES	July 2021	IPO	304m
Natural Killer	 SHORELINE biosciences	June 2021	Strategic Partnership	2.3b
Macrophages	 carisma THERAPEUTICS	March 2021	Series B	59m
Natural Killer	 nkarta THERAPEUTICS	July 2020	IPO	252m

Recent Commercial Activity for iNKT Cell Therapies

Acquisition

May 2021
US\$70m upfront
US\$115m milestone payments



Early Phase 1

Capital Raise

May 2021
US\$52m
Series A









Pre-clinical

- The CAR-T Cell Therapy market is expected to reach ~US\$13.6 billion by 2026 growing at a CAGR of 56.2% from 2018 to 2026¹

1. <https://www.businesswire.com/news/home/20191120005904/en/Global-CAR-T-Cell-Therapy-Market-Analysis-Report-2019---Market-Anticipated-to-Record-a-CAGR-of-56.2-During-2018-2026---ResearchAndMarkets.com>

Valuation of Early-Stage Cell Therapy Companies

Company	Exchange	Valuation (AU\$m) ¹	Number of Cell Therapy Products ²	Stage of Lead Cell Therapy
	NASDAQ	\$1282	5	Phase 1
	NASDAQ	\$1910	3	Phase 1
	NASDAQ	\$1080	5	Phase 1
	NASDAQ	\$528	4	Phase 1
	ASX	\$116	2	Phase 1
	ASX	\$148	3	Preclinical

1. As of Sep 6, 2021

2. Companies may have additional non-cell therapy products

CAR-iNKT Cell Therapy Development

12 – 24 months

- Recruit cell therapy manufacturing expert – Dr Sandhya Buchanan ✓
- Enter into Research Agreement with Imperial College London ✓
- Recruit domain expertise board members – Dr Debora Barton ✓
- Expand Scientific Advisory Board – Dr Reuben Benjamin; Dr John Maher ✓
- Select GMP manufacturer
- GMP manufacturing of CAR19-iNKT cells for phase 1 clinical trial
- FDA pre-IND meeting
- FDA IND clearance
- Dose first patient in Phase 1 clinical trial for non-Hodgkin's lymphoma
- Develop additional products using other CARs

Dr Sandhya Buchanan - VP Manufacturing and Quality



- Commenced with SUDA August 2021
- Previously Senior Director – Atara Biotherapeutics – (mkt cap US\$1.32 bn*)
- More than 20 years' experience in cell & gene therapy and vaccine manufacturing
- Dr Buchanan will lead the manufacturing efforts for the iNKT cell therapy platform
- PhD – Pharmaceutical Sciences
 - University of Colorado Health Sciences Center

** as of Sep 6, 2021*



Penn Medicine



iNKT Cell Therapy Platform Summary



Exclusive global rights - iNKT cell therapy platform

SUDA Pharmaceuticals Ltd has secured the exclusive, global rights to the iNKT cell therapy platform developed by Professor Anastasios Karadimitris, a clinical academic at Imperial College London, UK



CAR-iNKT cells are dual targeting

iNKT cells have a T cell receptor (TCR) that can bind to CD1d that is present on the surface of several cancer types. Introduction of a Chimeric Antigen Receptor (CAR) provides a second way to target cancer cells, increasing their activity



The first target will be cancers with CD19

CD19 is a well known target for cell therapy treatment that is expressed on numerous blood cancers. We will also target other cancers that express CD1d and potentially other disease areas



Potential to produce an 'off-the-shelf' product

iNKT cells have been shown to be protective against acute graft-versus host disease (GVHD). As such, the therapy may be produced from a healthy donor and delivered to many patients, potentially resulting in a more effective product



Improved manufacturing logistics

A major challenge for the cell therapy sector is the complex and costly supply chain. Having a product prepared from a healthy donor and stored prior to use will significantly improve the logistics and increase affordability

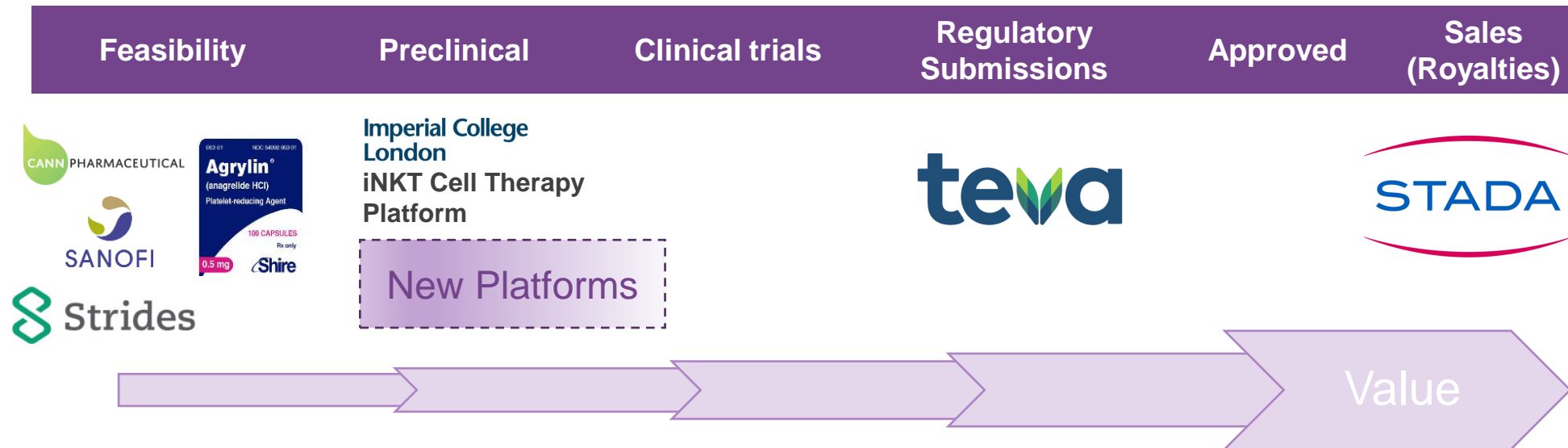


Commercial interest from large pharma

Cell therapies have had an enormous impact on the oncology field based on their impressive cure rates. A platform that provides dual targeting and 'off-the-shelf' dosing is expected to generate commercial interest from large pharma

Summary

- ZolpiMist commercialization (Teva, STADA, other territories) – Australia partner secured
- Integrate and develop new technologies – iNKT Cell Therapy Platform
- Identify and acquire new platform technologies
- Anagrelide formulation stabilisation
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Glossary

- **Antigen** = Any substance that induces the immune system to produce antibodies against it is called an antigen. Any foreign invaders, such as pathogens (bacteria and viruses), chemicals, toxins, and pollens, can be antigens.
- **alpha-galactosylceramide (aGalCer)** = is a specific ligand for human and mouse natural killer T cells. It is a synthetic glycolipid.
- **CAR** = Chimeric Antigen Receptor can be introduced into immune cells to target cancer cells.
- **CAR-T** = Chimeric Antigen Receptor T Cell.
- **iNKT** = invariant Natural Killer T cells are components of the immune system that seek and destroy foreign or abnormal cells.
- **TCR** = T Cell Receptors are group of proteins found on immune cells that recognise fragments of antigens as peptides bound to MHC complexes.
- **CD1d** = Cluster of differentiation 1, which is expressed on some immune cells and cancer cells.
- **CD19** = Cluster of Differentiation 19 is a protein that is expressed in a B cells and many cancer cell types.
- **Cell Therapy** = The use of intact cells to lessen or cure a disease. Cells may be from the patient (autologous) or from a healthy donor (allogenic).
- **Immuno-oncology** = The use of the immune system to treat cancer.
- **Invariant** = Never changing.
- **In vitro** = Work completed in a test tube or outside of an animal.
- **In vivo** = work completed using an organism (i.e. mouse, human).
- **Lymphomas** = Lymphoma is a cancer of the lymphatic system, which is part of the body's germ-fighting network.
- **Novel** = Of new or unusual kind.
- **Platform** = A systematic method to leverage prior knowledge for a given new therapy.