

## SUDA Presentation to Shareholders

14 October 2021

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### **Board & Senior Management**



### 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, nonexecutive director or CEO, of more than fifteen companies in the US, Australia and Asia. Mr Hopper has founded, or technology seeded, six companies on the ASX and Nasdaq.

CHIMERIC



### 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.







### **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.





#### **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.





### 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.





Viralytics

IMUGENE

# SUDA PHARMACEUTICALS LTD

# Agenda

Managing Director's address

- Q&A (via online platform)
- Formal Business

# Progress in 2021

- ZolpiMist<sup>®</sup> commercialization (Teva, STADA, other territories) Australian partner secured
- Integrate and develop new technologies iNKT cell therapy platform acquired
- Anagrelide formulation stabilisation
- Early-stage feasibility development work





# ZolpiMist<sup>®</sup> - Insomnia

- ZolpiMist is SUDA's oral spray version of the insomnia drug Ambien/Stilnox, Sanofi's blockbuster<sup>1</sup>
- Short-term insomnia has an estimated prevalence of 9.5% in the US<sup>2</sup>
- Sleep problems rose from 16% to 25% during the COVID-19 pandemic (University of Southampton)<sup>3</sup>
- STADA to commercialise SUDA's TGA approved ZolpiMist in Australia (upfront payments and a double-digit royalty on the improved spray unit)
- Current Licensee populations:
  - Teva: ~350 million
  - STADA: ~25 million
  - Discussions with additional territories are underway
- SUDA to supply finished product



ZolpiMist has been approved by the TGA and the FDA and SUDA holds the rights to ZolpiMist outside of North America https://www.ajmc.com/view/insomnia-overview-epidemiology-pathophysiology-diagnosis-and-monitoring-and-nonpharmacologic-therapy https://www.southampton.ac.uk/news/2020/08/sleeploss-lockdown.page







# iNKT Cell Therapy Platform – Highlights (acquired June 2021)

SUDA's invariant Natural Killer 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 provide 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)



# SUDA's iNKT Cell Therapy Platform



### **iNKT Cell Benefits**

- iNKT cells are one of the most potent types of immune cells, acting rapidly
- iNKT cells bridge the adaptive and innate immune system
- iNKT cells activate components of the immune system to fight cancer cells
- The iTCR is common to all people so iNKT cells do not cause graft versus host disease
- Our preclinical data strongly supports use of iNKT cells with chimeric antigen receptors (CAR) to treat cancer



## What are Chimeric Antigen Receptors (CARs)?

CD19-CAR

Target CD19





Immune cells are

harvested from the

healthy donor and the

collected

**iNKT Cell** 

**CD19** The iNKT cells are genetically reprogrammed with a CAR, supercharging them to seek out and destroy specific cancer cells

Once administered to the cancer patient, the CAR-iNKT cells can seek out and destroy the cancer cells and recruit other components of the immune system





### Different CARs to Target Different Cancers or Diseases



## CAR-iNKT Cell Therapy Development

### 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 Prof. Tassos Karadimitris (Chair); 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

### iNKT Cells Can Be Used Off The Shelf

Oncologics

Home > Topics > Precision Medicine > Allogene CAR-T Cancer Trials Placed on Clinical Hold by FDA

Gene Editing Gene Therapy

# Allogene CAR-T Cancer Trials Placed on Clinical Hold by FDA

News & Features

October 12, 2021

Precision Medicine

Oncology

While this news is unfortunate for Allogene, and others working with T cells to create allogeneic cell therapy products, this may be an advantage for SUDA's iNKT cell therapy technology. iNKT cells **do not** need additional gene editing to be used off the shelf. They are naturally able to be used that way. Allogene is working with T cells and they need to use TALEN® (others use CRISPR), which enables them to delete additional genes to make their product off the shelf. In the case of Allogene, they delete two genes, TCR $\alpha$  and CD52. While we do not have the whole story yet, it is conceivable that additional genetic engineering may compromise the cells, which may have led to the "chromosomal abnormality."





"SUDA has undergone several transformations over its 22-year history. In order to fully realise our potential, we believe it is important to revitalise our image to enable our key stakeholders to see us from a fresh perspective. We have inlicenced what we believe is a transformational cancer therapy from Imperial College London. We will continue to build out from here, targeting diseases ("**arrow**") with new (no**vella**) platforms to help patients live longer and healthier lives."

### Dr. Michael Baker

CEO and Managing Director





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# Special Business Resolutions

### Resolutions

- 1. Approval of change of Company name
- 2. Ratification and approval of previous allotment and issue of Shares
- 3. Approval of Employee Share Option Plan
- 4. Approval of allotment and issue of options to a related party: Dr. Michael Baker
- 5. Approval of issue of options to Baker Young Limited





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