**ASX: ALA**Arovella Therapeutics Limited
ACN 090 987 250



#### **ASX Release**

30 October 2025

#### INTERIM CHAIR'S ADDRESS AND CEO PRESENTATION TO ANNUAL GENERAL MEETING

**MELBOURNE, AUSTRALIA 30 October 2025:** Arovella Therapeutics Ltd (ASX: ALA), a biotechnology company focused on developing its invariant Natural Killer T (iNKT) cell therapy platform, provides the Interim Chair's address and CEO presentation for today's Annual General Meeting.

The meeting commences at 11:00am AEDT held virtually via an online platform. Full details of the meeting can be found in the Notice of Annual General Meeting dated 30 September 2025, available at <a href="https://www.arovella.com/asx-announcements">https://www.arovella.com/asx-announcements</a>.

Release authorised by the Managing Director and Chief Executive Officer of Arovella Therapeutics Limited.

Dr Michael Baker Chief Executive Officer & Managing Director Arovella Therapeutics Ltd Tel +61 (0) 403 468 187 investor@arovella.com **ASX: ALA**Arovella Therapeutics Limited
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#### **NOTES TO EDITORS:**

#### **About Arovella Therapeutics Ltd**

Arovella Therapeutics Ltd (ASX: ALA) is a biotechnology company focused on developing its invariant natural killer T (iNKT) cell therapy platform from Imperial College London to treat blood cancers and solid tumours. Arovella's lead product is ALA-101. ALA-101 consists of CAR19-iNKT cells that have been modified to produce a Chimeric Antigen Receptor (CAR) that targets CD19. CD19 is an antigen found on the surface of numerous cancer types. iNKT cells also contain an invariant T cell receptor (iTCR) that targets glycolipid bound CD1d, another antigen found on the surface of several cancer types. ALA-101 is being developed as an allogeneic cell therapy, which means it can be given from a healthy donor to a patient. Arovella is also expanding into solid tumour treatment through its CLDN18.2-targeting technology licensed from Sparx Group. Arovella will also incorporate its IL-12-TM technology into its solid tumour programs.

**Glossary: iNKT cell** – invariant Natural Killer T cells; **CAR** – Chimeric Antigen Receptor that can be introduced into immune cells to target cancer cells; **TCR** – T cell receptors are a group of proteins found on immune cells that recognise fragments of antigens as peptides bound to MHC complexes; **B-cell lymphoma** – A type of cancer that forms in B cells (a type of immune system cell); **CD1d** – Cluster of differentiation 1, which is expressed on some immune cells and cancer cells;  $\alpha$ **GalCer** – alpha-galactosylceramide is a specific ligand for human and mouse natural killer T cells. It is a synthetic glycolipid.

For more information, visit www.arovella.com

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 the actions of third parties and financial terms. These factors and assumptions are based upon currently available information, and the forward-looking statements herein speak only 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 forwardlooking 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; the 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.

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#### **Interim Chair's Address**

The order of events for today's Meeting will be as follows:

- I will firstly provide an overview of Arovella's performance during the 2025 financial year (FY25)
- We will then hear from the CEO and Managing Director, Dr Michael Baker
- We will then proceed with the formal business and the resolutions of the Meeting.

I joined Arovella's Board of Directors at a pivotal time in the company's history, which was shortly after licensing its invariant Natural Killer T (iNKT) cell platform from Imperial College London. At the conclusion of this financial year, Tom Duthy stepped down from the Arovella Board of Directors, and we wish him well for his future endeavours. I now have the pleasure of taking the interim Chair role for a second time, which is exciting as the company embarks on an important milestone, which will mark the first time the CAR-iNKT cell platform is included in a clinical trial for patients with CD19+ lymphoma and leukaemia. We have been busily working to secure a new board member capable of transitioning to Chair, who has an extensive background in drug development, spanning biotechnology and large pharmaceutical companies. We are pleased to have selected our preferred individual from a pool of exceptional candidates interested in joining the Company, and we look forward to announcing the new board member this quarter.

Arovella is well positioned for growth as we continue to make great steps building our pipeline to target a range of high unmet needs in solid tumours with a unique cell therapy. The progress we have made is largely due to the excellent work of our excellent team, which I will touch on more in just a moment, coupled with a capital raise, positioning the Company well to accelerate the development opportunities.

Firstly, let me thank all our shareholders for their continued faith and support of the Company. Drug development is a challenging process, especially when one is breaking new ground, with a unique technology that ultimately becomes the opportunity to create life altering therapies that drive shareholder returns. Despite a challenging start to the calendar year, combined with several sector-specific issues that suppressed the biotechnology sector, Arovella was delighted to raise \$15 million (before offer costs). This provides capital for Arovella to advance its programs and positions the Company for success and to move to its first clinical trial. Reflecting the sentiment of our shareholders, we too are disappointed by the decrease in share price over the course of CY25, but we are buoyed by the continued progress across our programs, superb enhancements to the team, and have confidence that the Company is more advanced and in a better position both financially and developmentally since the commencement of the year.

Since our last AGM, we have made significant progress for ALA-101, and we will hear more in a moment from Dr Michael Baker about the recent developments regarding our interactions with the FDA, and our planned milestones to take ALA-101 into phase 1 after receiving the acceptance of the IND from the FDA next year.

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Let me reiterate the importance of the IND. An accepted IND represents a significant advancement of Arovella's CAR-iNKT cell platform beyond the ability to commence the phase 1 clinical trial for ALA-101. The IND for ALA-101 will serve as the blueprint for the Arovella platform and all our future programs. ALA-105, for example, is our next product that includes a CLDN18.2 targeting CAR incorporated into our CAR-iNKT cells, which is being developed for gastric cancer and pancreatic cancer. Due to the work invested in defining the manufacturing process for ALA-101, the manufacturing process for ALA-105 is largely established and the only raw material that we will need to change is the lentivirus used to introduce the CAR. This is expected to reduce the amount of time and expenditure to take ALA-105, and all future programs, into clinical trials. This raises many possibilities for Arovella in the short term and represents an attractive platform for potential third-party partnering initiatives. Of significance, CLDN18.2 continues to be an important target for pharmaceutical companies, and we are pleased to be developing a unique CAR-iNKT cell therapy going after this target.

The Company continues to expand the focus on high unmet need solid tumours. This was highlighted through the Company securing an exclusive Option Agreement from Baylor College of Medicine for two new CARs, targeting solid tumour cancers of high unmet need. Should Arovella decide to proceed and exercise the Option and enter into a license agreement, this will add two new CARs targeting very important cancer types.

Lastly, the team has continued to grow. In readiness for the phase 1 clinical trial for ALA-101, Jacqueline Cumming was appointed as Senior Director of Clinical Development, and she joins us from an excellent pedigree having led clinical teams at both CSL and Peter MacCallum Cancer Centre. To enhance our R&D capacity, we welcomed Dr Clinton Heinze to drive the CLDN18.2 CAR-iNKT cell preclinical work within Professor Gianpietro Dotti's lab at the University of North Carolina. In addition, we appointed Dr Alfie Baker to establish our first research laboratory within the Jumar Bioincubator, to allow for the completion of preclinical studies and to generate data for our new programs.

At Arovella, the future is bright. The company is very well funded, each program is developing nicely, and we are on the precipice of the most important milestones in the company's history, namely receipt of the IND acceptance and the commencement of the phase 1 clinical study for ALA-101.

On behalf of my fellow directors, I would like to extend a heartfelt thank you to all our shareholders for their continued support and faith in the company. We look forward to striving to create additional shareholder value over the next twelve months and the years to come.Dr Elizabeth Stoner Non-Executive Interim Chair



### **Aroyella's Board of Directors**





Dr. Liz Stoner

**INTERIM CHAIR** 

Dr. Stoner is a distinguished biopharma executive, who brings decades of international industry experience to her role, including senior roles in Clinical Development Operations at Merck Research Laboratories. Liz is an Executive Partner at MPM Capital, and she has held numerous leadership roles at MPM portfolio companies. Liz was previously an Assistant Professor of Pediatrics at Cornell University Medical College.









Dr. Michael Baker
CEO & MANAGING DIRECTOR

Dr Baker has over 20 years of 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.











Dr. Debora Barton

### **DIRECTOR**

Dr. Barton has over 20 years of oncology experience, in academia, as a practicing physician and in the biotechnology / pharmaceutical industry. She served in key senior executive positions, including Carisma Therapeutics and Tscan Therapeutics, and Full-Life Technologies, where Debora is currently the Chief Medical Officer, and Advanced Accelerator Applications, acquired by Novartis during Debora's tenure.











Mr. Gary Phillips

### **DIRECTOR**

Mr. Phillips has more than 30 years of operational management experience in the pharmaceutical and healthcare industry in Europe, Asia and Australia. He is currently the CEO and Managing Director of the ASX-listed company, Syntara. Previously he was the CEO at Ciba Geigy in Hungary, which merged to form Novartis in 1996, where he led the successful launch of a portfolio of new products.









## Interim non-Executive Chair Address

Dr Elizabeth Stoner



## **CEO and MD Address**

Dr Michael Baker

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## Key achievements for FY 2025

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FY 2025 was a transformative year for Arovella and its proprietary iNKT cell platform



Completed key manufacturing activities for ALA-101 in preparation for phase 1 clinical trials



Completed regulatory steps and initiated clinical readiness for ALA-101 first-in-human clinical trials



Continued to enhance the CAR-iNKT cell platform and broaden its utility for more cancers

- All reagents required for manufacturing clinical batches sourced and ready
- Manufacturing runs performed in the GMP environment in readiness for Phase 1
- The manufacturing runs required for IND submission have been completed

- Substantial progress compiling the Investigational New Drug Application (IND) in preparation for submission
- Type D meeting held with the FDA to confirm the pathway forward for IND submission
- Selected Contract Research Organisation (CRO) as our partner for the phase 1 clinical trial

- Generated encouraging data for the CLDN18.2-targeted CAR in T cells
- Entered into an Exclusive Option with Baylor College of Medicine for two new CARs targeting GD2 (neuroblastoma) and GPC3 (hepatocellular carcinoma)
- Continued to search universities and research institutes globally for novel technologies to enhance the CAR-iNKT cell platform

### **Financial overview**

### Financial Snapshot

ASX CODE	ALA			
Market capitalisation <sup>1</sup>	\$113.72 million			
Shares on issue	1,197.0 million			
52-week low / high	\$0.068 / \$0.210			
Cash Balance (30 Sep, 2025)	\$21.9 million			

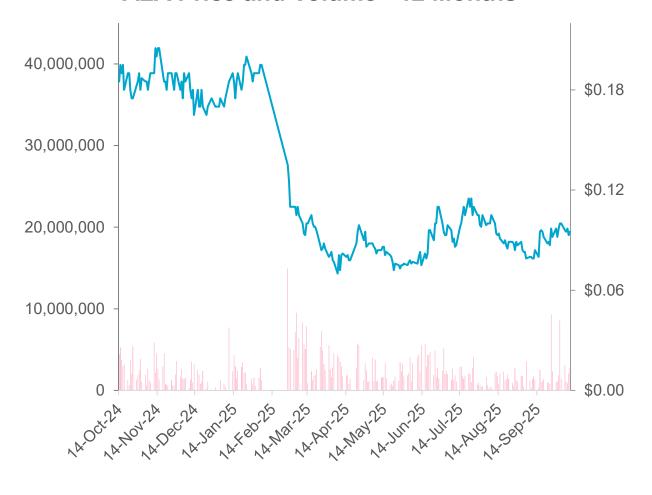
### **Major Shareholders**

Shareholder	Ownership (%) <sup>2</sup>			
BIOTECH CAPITAL MANAGEMENT <sup>3</sup>	68,677,966 (5.78%)			
RICHARD JOHN MANN <sup>4</sup>	68,487,674 (5.76%)			
NETWEALTH INVESTMENTS LIMITED WRAP SERVICES A/C	32,788,389 (2.76%)			
NETWEALTH INVESTMENTS LIMITED SUPER SERVICES A/C	30,519,572 (2.57%)			
UBS NOMINEES PTY LTD	29,070,196 (2.45%)			

### 1. As of 10 October 2025

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### ALA Price and Volume - 12 Months<sup>1</sup>



<sup>2.</sup> As of 22 August 2025 - Appendix 4E and Annual Report

<sup>3.</sup> Formerly Merchant Funds Management

<sup>4.</sup> Holding includes associated entities and parties

## Recent cell therapy transactions<sup>1</sup>

Date	Type of deal	Acquirer/Licensee	Target/Licensor	Cell Type	Stage	Upfront (US\$M)	Milestones (US\$M)	Total deal value (US\$M)
Oct-25	Acquisition	ر <sup>ال</sup> Bristol Myers Squibb	ORBITAL	In vivo CAR	Preclinical	\$1,500	\$0	\$1,500
Aug-25	Acquisition	Kite A GILEAD Company	interius	In vivo CAR	Phase 1	\$350	\$0	\$350
Jun-25	Acquisition	abbvie	<b>€capstan</b> tx <sup>™</sup>	In vivo CAR	Phase 1	\$2,100	\$0	Up to \$2,100
Mar-25	Acquisition	AstraZeneca 🕏	EsoBiotec	In vivo CAR	Phase 1	\$425	\$575	\$1,000
Nov-24	Acquisition	Roche	POSEIDA THERAPEUTICS	Allo T cell	Phase 1	~\$1,038	~\$462	\$1,500
Dec-23	Acquisition	AstraZeneca 🕏	GRACELL	T Cell	Phase 1b	\$1,000	\$200	\$1,200
Aug-23	Licence <sup>2</sup>	IMUGENE Developing Cancer Immunotherapies	PRECISION BIOSCIENCES	T Cell	Phase 1b	\$21	\$206	\$227
Aug-23	Strategic investment (ROFR) <sup>3</sup>	**astellas	POSEIDA THERAPEUTICS	T Cell	Phase 1	\$25	\$0	\$25
May-23	Licence	Janssen <b>T</b>	Cellular Biomedicine Group	T Cell	Phase 1b	\$245	undisclosed	
Jan-23	Acquisition	AstraZeneca	neo/gene	T Cell	Phase 1	\$200	\$120	\$320
Oct-22	Development collaboration <sup>4</sup>	<b>GILEAD</b>	ARCELLX	T Cell	Phase 2	\$225	undisclosed	
Aug-22	Licence & strategic collaboration	Roche	POSEIDA THERAPEUTICS	T Cell	Phase 1	\$110	\$110	\$220
Sep-21	Development collaboration	Genentech  A Member of the Roche Group	<b>%</b> Adaptimmune	T Cell	Preclinical	\$150	\$150	\$300
Aug-21	Research collaboration	Kite A GILEAD Company	APPIA BIO	iNKT Cell	Preclinical	undisclosed	undisclosed	\$875
May-21	Acquisition	Athenex	»kuur <sup>*</sup>	iNKT Cell	Phase 1	\$70	\$115	\$185

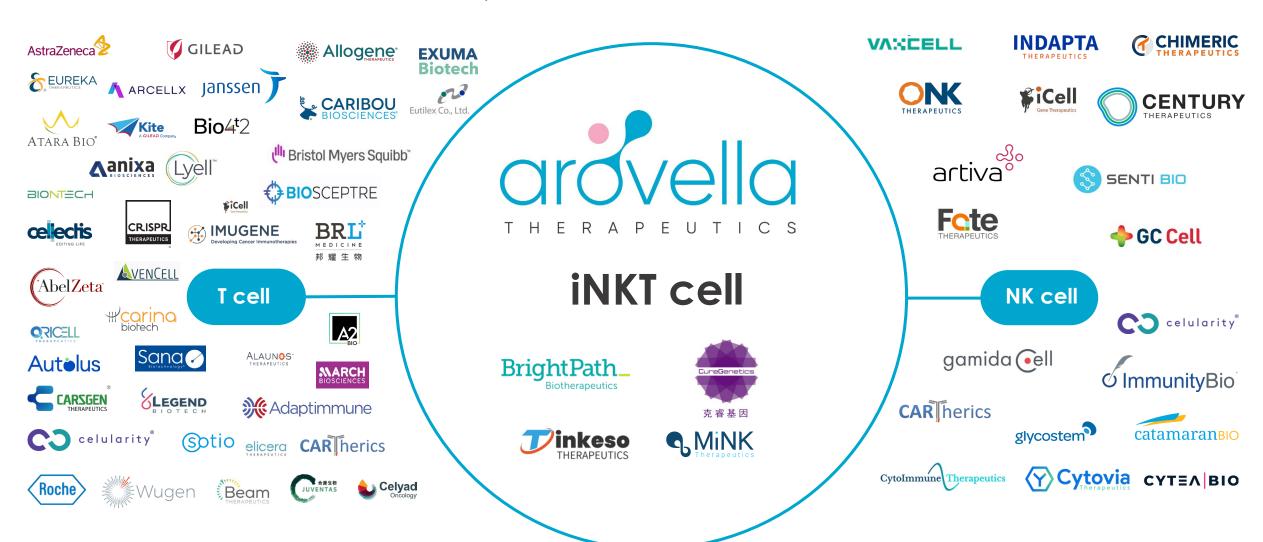


<sup>1.</sup> See the last slide for deal references; 2. Precision is eligible for double digit royalties on net sales and \$145 million in milestone payments and tiered royalties for additional programs; 3. Poseida also received a US\$25m equity investment from Astellas; 4. Arcellx also received a US\$100m equity investment from Gilead

## A differentiated position

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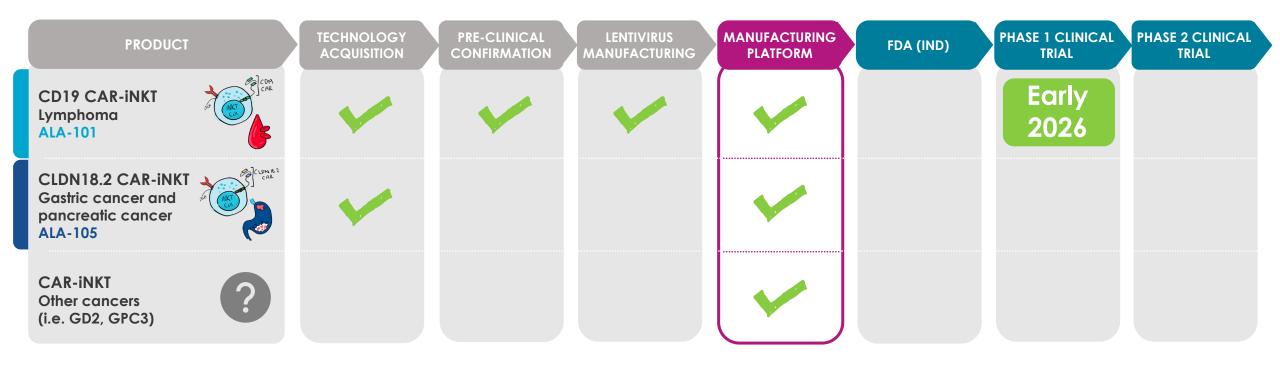
T cell and NK cell sectors are competitive





## Arovella's path to patient





ALA-101 Pre-IND FDA meeting completed, and clinic-ready manufacturing process established

Arovella held a positive Type D
meeting with the FDA and based
on feedback intends to file its
IND in CY2025

Acceptance of the IND for ALA-101 provides the roadmap for all future CAR-iNKT products targeting different cancers

## Pathway to US FDA IND

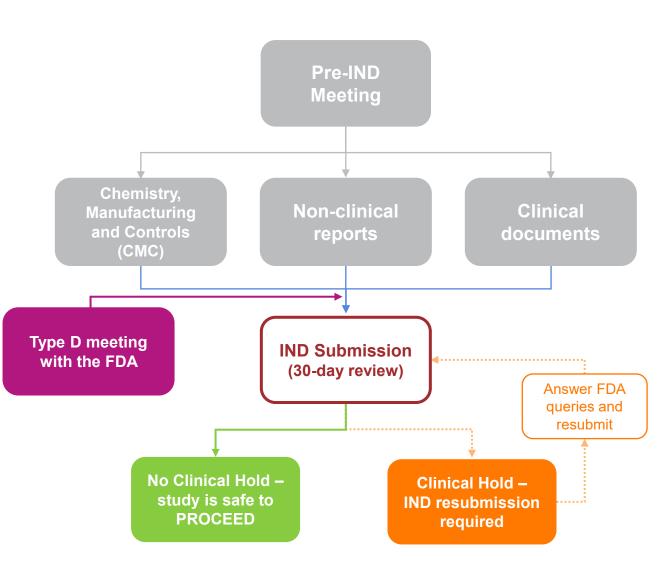
Arovella is working to have the highest chance of IND acceptance

Early interactions with the FDA to discuss the proposed clinical program

Generation of data for manufacturing and nonclinical studies. Study reports generated and IND is prepared, including clinical documents

Investigational New Drug (IND) application submitted to the FDA

FDA outcome is reached, and the study is approved, or the IND receives a clinical hold



### Interaction with the FDA

Positive Type D meeting held



Arovella elected to hold a **Type D meeting** with FDA to obtain additional feedback on testing requirements for a key cGMP reagent



During the meeting, FDA provided clear guidance on testing requirements for the reagent



Much of the testing required has already been completed, with Arovella now working to complete the additional testing and file the IND this quarter

## Taking ALA-101 into first-in-human trials

ALA is progressing towards its ALA-101-001 phase 1 study



First patient dosed with ALA-101

Ethics approval for ALA-101-001 study in Australia

Complete manufacturing of clinical batches of ALA-101

File IND application with US Food and Drug Administration (FDA)

Select and contract clinical trial sites

Finalise clinical trial Protocol and Investigator's Brochure

Contract CRO to support ALA-101-001 first-in-human trial

Conduct Type D meeting with FDA to align on reagent testing for IND filing

Form Clinical Advisory Board and consult with KOLs to inform clinical trial design

Complete IND-enabling non-clinical studies to support the safety and efficacy of ALA-101



## ALA-101-001: study design



Part 1 Part 2

### **Dose escalation**

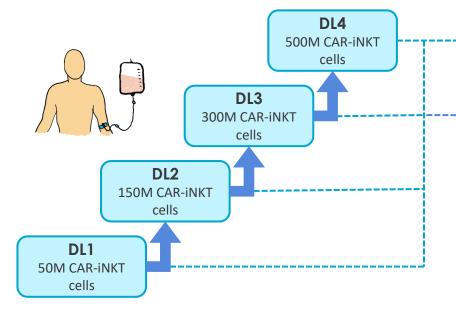
4 dose levels

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- 13-21 participants expected
- CD19+ lymphoma

### Dose expansion

- Dose level(s) selected from Part 1
- Up to 22 participants
- CD19+ lymphoma and leukaemia



Dose TBD based on Part 1 data

Dose TBD based on Part 1 data Possibility to enrol patients at two dose levels, depending on preliminary efficacy data from Part 1

### **Primary objectives**

To evaluate the safety and tolerability of ALA-101 in adult patients with CD19+ non-Hodgkin's Lymphoma (NHL) or leukemia

### Secondary objectives

- To determine the maximum tolerated dose (MTD) for progression into next stages of clinical studies
- To evaluate the preliminary efficacy of ALA-101
- To characterise the pharmacokinetic (PK) profile of ALA-101
- To evaluate the immunogenicity of ALA-101

Abbreviations: M, million



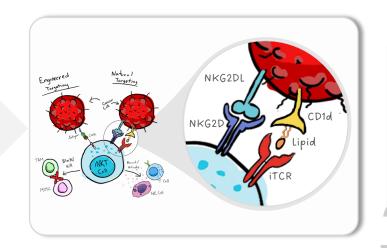
## iNKT cells are well placed to tackle solid tumours



iNKT cells have features that may make them useful for treating solid tumours

## Naturally target cancer markers and are prognostic for survival

iNKT cells naturally target CD1d, NKG2DL and other markers present on some tumour types. iNKT cell levels are prognostic for colorectal cancer and head and neck squamous cell carcinoma.<sup>1,2</sup>

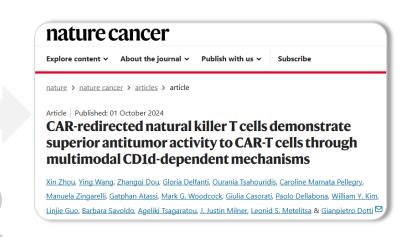


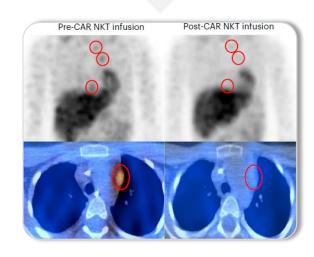
## Infiltrate tumours and have shown promising clinical data in human solid tumour studies

iNKT cells have been shown to infiltrate solid tumours and have shown promising data when tested in human clinical studies for a range of solid tumours, including neuroblastoma and renal cell carcinoma.<sup>5,6</sup>

## Kill pro-tumour cells, activate helpful immune cells and outperform CAR-T cells

iNKT cells can influence the TME, induce cross-priming of other immune cells<sup>3</sup>, and CAR-iNKT cells have been shown to outperform CAR-T cells when tested using mouse models.<sup>4</sup>





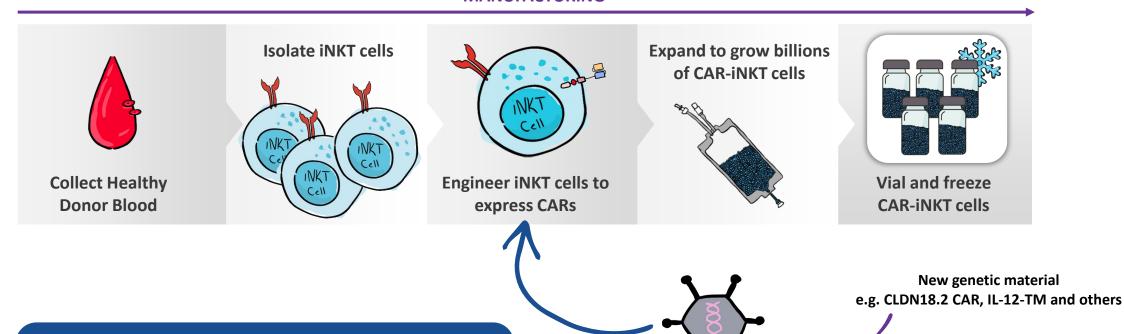


## Add additional CARs for novel targets

New CARs

Arovella's manufacturing process can be leveraged for multiple cancer types

#### **MANUFACTURING**



Arovella has a clinic-ready manufacturing process to manufacture CAR-iNKT cells

which can be leveraged to create many CAR-iNKT

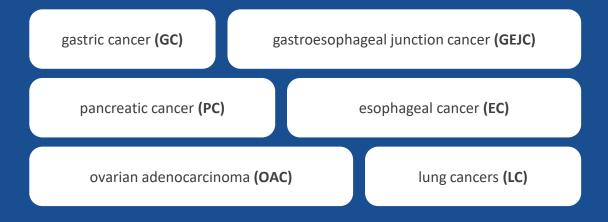


## Introducing Claudin 18.2 (CLDN18.2)

A promising solid tumour target



## identified in several types of cancers





### Validated target

with first monoclonal antibody approved in Japan and the US in 2024



### Gastric cancer

market alone expected to reach

\$10.7 billion by 20311



## Successfully generated a functional CAR

that targets **CLDN18.2** 

<sup>1.</sup> https://www.alliedmarketresearch.com/gastric-cancer-market-A74458#:~:text=The%20global%20gastric%20cancer%20market,cells%20lining%20of%20the %20stomach

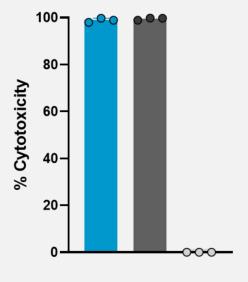
## Arovella's CLDN18.2-targeting CAR is highly active

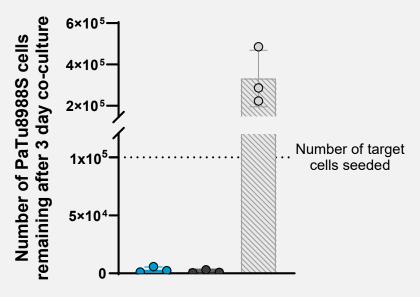


The CLDN18.2 CAR derived from SPX-101 mediates potent cytotoxicity in T cells

- The licensed CLDN18.2-specific mAb, SPX-101, was converted to a scFv and formatted as a CAR.
- The activity of Arovella's newly created CLDN18.2 CAR was tested in T cells for the ability to kill pancreatic cancer cells (PaTu8988S) expressing CLDN18.2 antigen on their surface.
- Arovella's CLDN18.2 CAR demonstrates potent and specific killing of PaTu8988S target cells, equivalent to a control CAR (CT041) expected to display robust killing and currently under clinical evaluation, and relative to T cells lacking a CAR (non-transduced T cells).

- Arovella CLDN18.2 CAR-T
- Control CT041 CAR-T
- Non-transduced T cells





CAR-T cells manufactured from n=3 donors

Next, the CAR will be incorporated into iNKT cells using Arovella's CAR-iNKT cell manufacturing process



## Taking ALA-105 to IND filing

ALA is progressing nonclinical development of ALA-105



File IND with the FDA or other suitable regulator

Complete IND-enabling studies

Complete Process Development to manufacture ALA-105

Manufacture GMP CLDN18.2 CAR lentivirus

Incorporate IL-12-TM into the CLDN18.2 CAR-iNKT cells and complete mouse models

Incorporate the CLDN18.2 CAR into iNKT cells and evaluate anti-tumour potential in vitro

Generate CAR-T cells with the CLDN18.2-targeting CAR and confirm functionality

Develop in vitro and in vivo models to test CLDN18.2 CAR-engineered cells

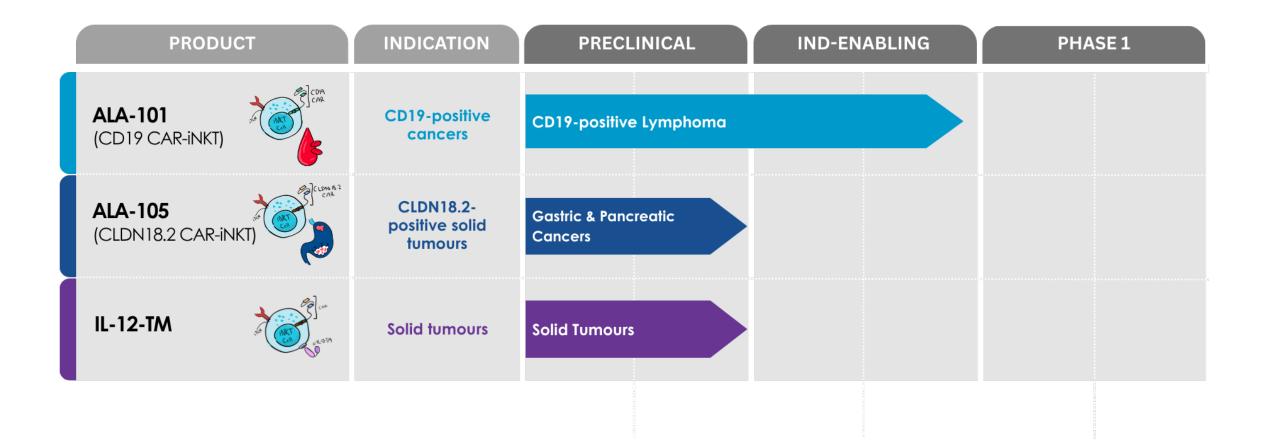
Convert the antigen-binding domains from the antibody into a short-chain variable fragment (scFv) and format as a CLDN18.2 CAR

License a CLDN18.2-specific monocloncal (mAb) antibody for use in cell therapies



## Arovella's expanding pipeline







## Chair appointment

A rigorous process was undertaken to identify a world class addition to the ALA Board

- Exceptional candidate identified and selected negotiating the final details
- Previously at a high-profile Australian life sciences pharmaceutical company
- Deep scientific and commercial background
- Experience in biotech operations, strategy, capital raising and M&A
- Will join as a non-Executive director with the anticipated transition to non-Executive Chair
- Appointment expected this quarter



## **Upcoming milestones for FY2026**

Dec 2025







- Complete IND-enabling studies and file an IND application with US FDA for Phase 1
- Complete preparatory activities for a first-in-human phase 1 study for ALA-101 in patients with CD19+ blood cancers

Complete manufacturing of clinical batches and commence phase 1 study and generate initial data from patients in early dose cohorts



Arovella is funded to obtain preliminary safety and efficacy readouts for its phase 1 study of ALA-101



- Optimise the CLDN18.2 CAR for solid tumours and integrate into iNKT cells
- Test CLDN18.2 targeting CAR-iNKT cells in gastric cancer and pancreatic cancer models

- Confirm in vivo efficacy of CLDN18.2 targeting CARiNKT cells in gastric cancer and pancreatic cancer animal models
- Commence activities to manufacture ALA-105 for clinical trials (e.g. lentiviral vector production)

### IL-12-TM Integration

Integrate IL-12-TM into solid tumour programs and test benefits in anti-tumour efficacy models

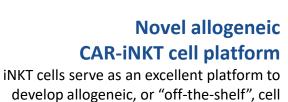
### **Pipeline Expansion**

- Continue to identify and acquire novel technologies that enhance and expand Arovella's iNKT cell therapy platform
- Option with Baylor College of Medicine to be exercised by Nov 2025



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## **Summary**



therapies to treat cancer

## **CAR-iNKT cells have anticancer properties**

CAR-iNKT cells have multiple anticancer properties that may support enhanced efficacy over other immune cell types, particularly against solid tumours



# Arovella's CAR-iNKT Cell

**Platform** 



## Lead product progressing to clinical trials

ALA-101, a potential treatment for CD19expressing blood cancers, is being progressed to phase 1 clinical trials, expected to commence in early 2026



Arovella continues to expand the iNKT cell platform with the addition of a CLDN18.2 targeting CAR and its IL-12-TM armouring

## Clinic-ready manufacturing process

Arovella has successfully developed a proprietary clinic-ready manufacturing process to produce CAR-iNKT cells



### Arovella is poised for growth

Arovella is developing a cutting-edge CAR-iNKT cell therapy platform, with an expanding pipeline and a strong leadership team



## Cell therapy deal references

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