

ASX: ALA

Arovella Therapeutics Limited
ACN 090 987 250



ASX Release

15 November 2024

CHAIRMAN'S ADDRESS AND CEO PRESENTATION TO ANNUAL GENERAL MEETING

MELBOURNE, AUSTRALIA 15 November 2024: Arovella Therapeutics Ltd (ASX: ALA), a biotechnology company focused on developing its invariant Natural Killer T (iNKT) cell therapy platform, provides the Chairman's address and CEO presentation for today's Annual General Meeting.

The meeting commences at 11:00am AEDT at the offices of Thomson Geer, Level 23, Rialto South Tower, 525 Collins Street, Melbourne, Victoria 3000, Australia. Full details of the meeting can be found in the Notice of Annual General Meeting dated 9 October 2024, available at <https://www.arovella.com/asx-announcements>.

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

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 (iTTCR) 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; **aGalCer** – 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 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; 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.

Chairman'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 2024 financial year (FY24)
- We will then proceed with the formal business and the resolutions of the Meeting
- We will then hear from the CEO and Managing Director, Dr Michael Baker
- After this there will be an opportunity for any general shareholder questions.

Since joining the board approximately eighteen months ago, I feel as enthused, if not more so, about the company as I did upon joining. Your Company is well positioned for growth as we take our lead program, ALA-101, into first-in-human clinical trials, while building a robust pipeline of oncology programs. The progress we have made is largely due to the excellent work from the team, which I will touch on more in just a moment, coupled with the Company raising additional capital in a timely and effective manner to allow us to focus on accelerating our development opportunities.

Firstly, let me thank all our shareholders for their continued support and faith in the Company. Despite the headwinds that have faced the biotechnology sector, Arovella was fortunate to raise \$12.5 million (before offer costs) in a highly supported Placement, providing capital for Arovella to advance its programs and position the Company for success. We are also pleased with the strong performance of the share price during FY24 and through the first five months of FY25, bucking the broader trend of many small-cap biotechnology companies.

Since our last AGM, we have made significant progress for ALA-101, advancing it towards first-in-human clinical trials. We completed the manufacture of the GMP lentivirus, a key component used to make our CAR-iNKT cells. The lentivirus delivers the DNA directly into the iNKT cells, programming them to make the CAR, the armed missile of the cells, which then enables the iNKT cells to target and destroy tumour cells. We were delighted to have this completed earlier this year, as it is a key component that feeds into our GMP manufacturing of ALA-101.

Secondly, we were able to complete process development for the manufacturing of ALA-101. This is a terrific achievement for the Company and has been a considerable focus since licensing the platform from Imperial College London. Having this step completed means that we have a robust manufacturing process, capable of producing large amounts of highly pure CAR-iNKT cells using well-known and automated equipment. Importantly for the Company, it means that for any additional programs that we work on, the manufacturing piece is largely completed and the only raw material that we will need to change for a new product is the lentivirus. This opens up many possibilities for Arovella in the short term and represents an attractive platform for potential third-party partnering initiatives.

With the completion of manufacturing process development, combined with the strong preclinical data that we have generated to demonstrate the efficacy of the CAR19-iNKT cells, it meant we were ready to approach the key regulatory body, the US Food and Drug Administration (FDA), to hold our pre-Investigational New Drug Application, or pre-IND, meeting for ALA-101. Yet again, the team did a sensational job preparing the briefing materials, and the meeting was positive for Arovella's plans moving forward. The agency was supportive of our proposed development plans and proposed clinical trial

strategy, leaving us optimistic about an IND filing in the first quarter of the 2025 calendar year. Having an IND secured is a critical step, enabling Arovella to commence our Phase 1 clinical trial for ALA-101.

In preparation of our first-in-human Phase 1 clinical trial, we assembled a world class Clinical Advisory Board (CAB), to secure their input for the clinical trial design, and to assist us in conducting a trial that can achieve key company objectives. The CAB consists of Dr Sam Fiorenza, Deputy Director and Cell Therapy Lead at Epworth Healthcare; Dr Debora Barton, also my fellow board member, who has a wealth of experience in designing and running early-stage CAR-T clinical trials; and lastly, Professor Sattva Neelapu, who played an enormous role in the approval of the most successful CAR-T product to date, Yescarta[®]. With all the pieces coming together nicely, we look forward to providing updates on the clinical plans for ALA-101 in due course.

We are not stopping with ALA-101. To position Arovella on the global stage, we have continued to take steps in developing assets to tackle solid tumours. We announced late last year that we licensed a novel monoclonal antibody (mAb) sequence from Sparx Group that targets claudin 18.2, which is on the surface of gastric cancer, pancreatic cancer and several other solid tumours. This is a very hot target for pharmaceutical companies, with the recent approval of the first monoclonal antibody called zolbetuximab, brand name Vyloy[®], targeting this receptor. We believe a claudin 18.2 iNKT cell therapy potentially offers additional cancer killing effects over and above monoclonal antibodies.

In addition, we supplemented our cell therapy portfolio by licensing a novel armouring strategy from the lab of Professor Gianpietro Dotti at the University of North Carolina Lineberger Comprehensive Cancer Center. This is IL-12-TM, which we expect will enhance the activity of our CAR-iNKT against solid tumours, which we believe is important to achieve the best outcome for solid tumour cancer patients. We will continue to scour the globe for novel and validated CARs, as well as technologies that will enhance the persistence of CAR-iNKT cells, providing them with the best chance of success in solid tumours. We look forward to providing updates on the new programs and data that we generate.

We have also continued to strategically strengthen the team. We added Dr Michelle Ferguson and Dr Kelvin Yip to the group to drive our R&D efforts, and they have both hit the ground running, providing critical input into the activities of the Company. In addition, we strengthened our Scientific Advisory Board, through the appointment of Professor Gianpietro Dotti, a CAR-iNKT cell therapy pioneer who we're lucky to have input from. There was also a Board change during the financial year, with Mr David Simmonds retiring from the Company at last year's AGM. On behalf of all Directors and staff of Arovella we thank David for his contribution to the business during his tenure.

The 2024 financial year has been an outstanding year for Arovella. We are well funded to move our lead program into Phase 1 clinical trials and start dosing patients, which will represent a very material development for the Company.

Over the next year, we are keen to see the performance of ALA-101 in clinical trials, and we will continue to press on our new programs, as well as secure those that we think can be developed to assist cancer patients in need.

ASX: ALA

Arovella Therapeutics Limited
ACN 090 987 250



Thank you again 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 Thomas Duthy
Non-Executive Chairman

ASX:ALA



Annual General Meeting

November

2024



Arovella's Board of Directors



Dr. Tom Duthy
CHAIRMAN

Dr Duthy has over 18 years of direct financial markets experience and is the Founder and CEO of Nemean Group Pty Ltd, a boutique corporate advisory and investor relations firm specialising in the life sciences and technology sectors. Tom spent ten years as a leading sell-side Healthcare & Biotechnology analyst at Taylor Collison Limited, focused mainly on small caps. companies.



Dr. Michael Baker
CEO & MANAGING DIRECTOR

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.



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, TScan Therapeutics and Advanced Accelerator Applications, acquired by Novartis during Debora's tenure.



Dr. Elizabeth Stoner
DIRECTOR

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.



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 (Merged to form Novartis in 1996) where he led the successful launch of a portfolio of new products.





CEO & MD address

Disclaimer

1. The information in this presentation does not constitute personal investment advice. The presentation is not intended to be comprehensive or provide all information required by investors to make an informed decision on any investment in Arovella Therapeutics Limited (Company). In preparing this presentation, the Company did not take into account the investment objectives, financial situation and particular needs of any particular investor.
2. Further advice should be obtained from a professional investment adviser before taking any action on any information dealt with in the presentation. Those acting upon any information without advice do so entirely at their own risk.
3. Past performance information given in this presentation is given for illustrative purposes only and should not be relied upon as (and is not) an indication of future performance. The presentation includes forward-looking statements regarding future events and the future financial performance of Arovella. Forward looking words such as “expect”, “should”, “could”, “may”, “predict”, “plan”, “will”, “believe”, “forecast”, “estimate”, “target” or other similar expressions are intended to identify forward-looking statements. Any forward-looking statements included in this document involve subjective judgment and analysis and are subject to significant uncertainties, risks and contingencies, many of which are outside the control of, and are unknown to, Arovella and its officers, employees, agents or associates. In particular, factors such as outcomes of clinical trials and regulatory decisions and processes may affect the future operating and financial performance of Arovella. This may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. The information also assumes the success of Arovella’s business strategies. The success of the strategies is subject to uncertainties and contingencies beyond control, and no assurance can be given that the anticipated benefits from the strategies will be realised in the periods for which forecasts have been prepared or otherwise. Given these uncertainties, you are cautioned to not place undue reliance on any such forward looking statements. Arovella is providing this information as of the date of this presentation and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise.
4. Whilst this presentation is based on information from sources which are considered reliable, no representation or warranty, express or implied, is made or given by or on behalf of the Company, any of its directors, or any other person about the accuracy, completeness or fairness of the information or opinions contained in this presentation. No responsibility or liability is accepted by any of them for that information or those opinions or for any errors, omissions, misstatements (negligent or otherwise) or for any communication written or otherwise, contained or referred to in this presentation.
5. Neither the Company nor any of its directors, officers, employees, advisers, associated persons or subsidiaries are liable for any direct, indirect or consequential loss or damage suffered by any person as a result of relying upon any statement in this presentation or any document supplied with this presentation, or by any future communications in connection with those documents and all of those losses and damages are expressly disclaimed.
6. Any opinions expressed reflect the Company’s position at the date of this presentation and are subject to change.
7. This document does not constitute an offer to sell, or a solicitation of an offer to buy, securities in the United States or any other jurisdiction in which it would be unlawful. The distribution of this presentation in jurisdictions outside Australia may be restricted by law and any such restrictions should be observed.

Key achievements for FY2024

FY24 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 the manufacture of GMP lentiviral vector for ALA-101
- Completed process development work for the manufacture of ALA-101
- Commenced activities to manufacture GMP ALA-101 for first-in-human clinical trials



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

- Conducted a pre-IND meeting with the FDA and received support for the plans to take ALA-101 into phase 1 first-in-human clinical trials
- Engaged with clinicians and clinical trial sites, PIs and KOLs interested in being involved in the phase 1 study
- Assembled a world class Clinical Advisory Board to get input into the phase 1 trial design



Continued to enhance the iNKT cell platform and create shareholder value

- In-licensed a novel target for solid tumours (Claudin 18.2)
- In-licensed a cytokine technology which enhances the persistence and activity of CAR-iNKT cells
- 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 ¹ | \$211.51 million |
| Shares on issue | 1,057.6 million |
| 52-week low / high ¹ | \$0.080 / \$0.210 |
| Pro-forma Cash Balance (30 Sep, 2024) ² | \$13.2 million |

Major Shareholders

| Shareholder | Ownership (%) ³ |
|------------------------------------|----------------------------|
| BIOTECH CAPITAL MANAGEMENT PTY LTD | 109,709,355 (10.49%) |
| RICHARD JOHN MANN | 64,458,288 (6.14%) |
| UBS NOMINEES PTY LTD | 25,620,196 (2.45%) |
| BLACKBURNE CAPITAL PTY LTD | 21,227,306 (2.03%) |
| MR JAMES EVAN HUGHES-MORRIS | 19,688,196 (1.87%) |

1. As of 13 November 2024





























2. Including \$3m received through the R&D tax incentive rebate post Sep 30 announced Oct 25, and an additional \$300k expected for its Advanced Overseas Finding

3. As of 14 October 2024

ALA Price and Volume - 12 Months¹



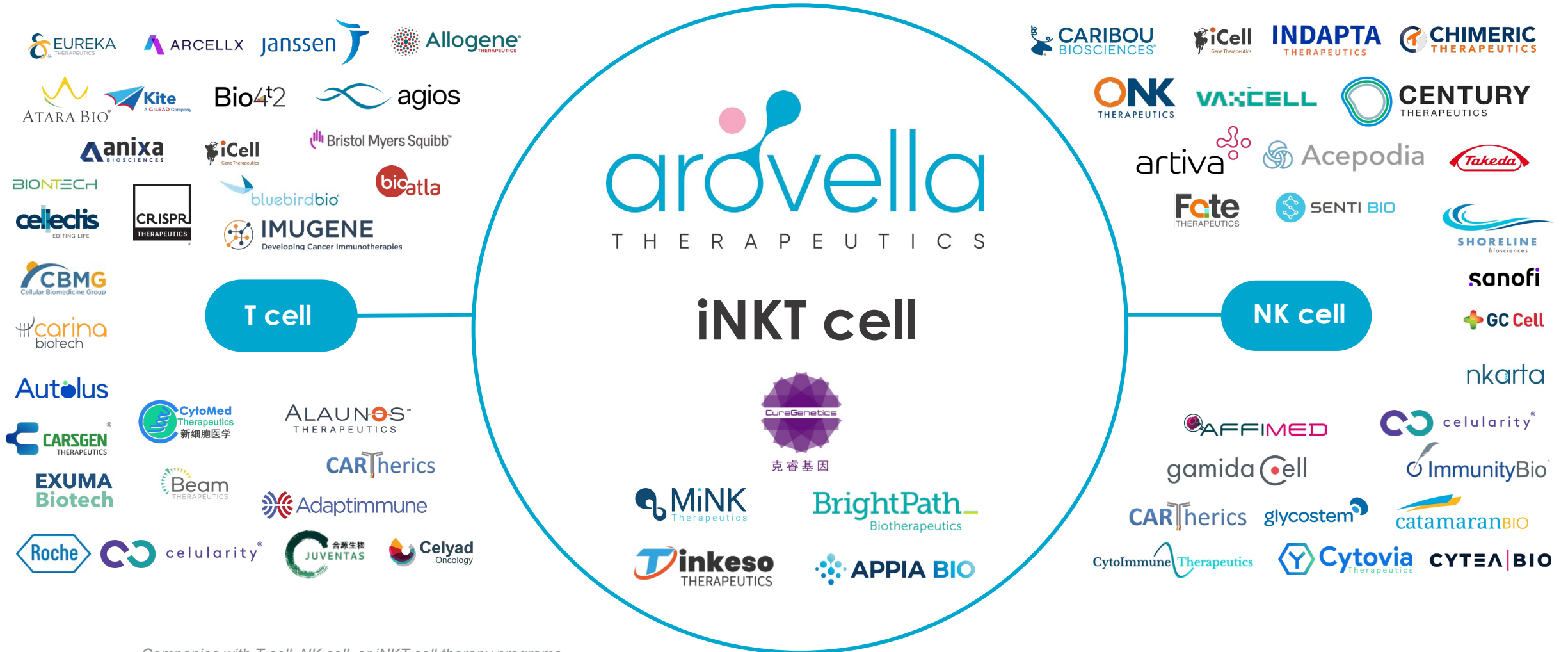
Recent cell therapy transactions¹

| Date | Type of deal | Acquirer/Licensee | Target/Licensors | Cell Type | Stage | Upfront (US\$M) | Milestones (US\$M) | Total deal value (US\$M) |
|--------|---|---|---|---------------|-------------|--------------------|----------------------|--------------------------|
| May-24 | Research collaboration |  XYPHOS |  POSEIDA THERAPEUTICS | T cell | TBD | \$50 | \$550 | \$600 |
| Dec-23 | Acquisition |  AstraZeneca |  GRACELL | T Cell | Phase 1b | \$1,000 | \$200 | \$1,200 |
| Nov-23 | Collaboration and investment ² |  AstraZeneca |  cellectis | Not specified | Platform | \$25 | \$70-220 per product | |
| Aug-23 | Licence ³ |  IMUGENE <small>Developing Cancer Immunotherapies</small> |  PRECISION BIOSCIENCES | T Cell | Phase 1b | \$21 | \$206 | \$227 |
| Aug-23 | Strategic investment (ROFR) ⁴ |  astellas |  POSEIDA THERAPEUTICS | T Cell | Phase 1 | \$25 | \$0 | \$25 |
| May-23 | Licence |  janssen |  CBMG <small>Cellular Biomedicine Group</small> | T Cell | Phase 1b | \$245 | <i>undisclosed</i> | |
| Jan-23 | Acquisition |  AstraZeneca |  neogene THERAPEUTICS | T Cell | Phase 1 | \$200 | \$120 | \$320 |
| Oct-22 | Development collaboration ⁵ |  GILEAD |  ARCELLX | T Cell | Phase 2 | \$225 | <i>undisclosed</i> | |
| Sep-22 | Research collaboration |  Genentech <small>A Member of the Roche Group</small> |  ArsenalBio | T Cell | Preclinical | \$70 | <i>undisclosed</i> | |
| Aug-22 | Licence & strategic collaboration |  Roche |  POSEIDA THERAPEUTICS | T Cell | Phase 1 | \$110 | \$110 | \$220 |
| Sep-21 | Development collaboration |  Genentech <small>A Member of the Roche Group</small> |  Adaptimmune | T Cell | Preclinical | \$150 | \$150 | \$300 |
| Aug-21 | Research collaboration |  GILEAD |  APPIA BIO | iNKT Cell | Preclinical | <i>undisclosed</i> | <i>undisclosed</i> | \$875 |
| May-21 | Acquisition |  Athenex |  kuur THERAPEUTICS | iNKT Cell | Phase 1 | \$70 | \$115 | \$185 |
| Jun-21 | Acquisition |  eterna |  Novellus THERAPEUTICS | Multiple | Preclinical | \$125 | \$0 | \$125 |

1. See the last slide for deal references; 2. Cellectis will receive a US\$220m equity investment from Astra Zeneca plus tiered royalties. Milestones are payable for 10 products; 3. Precision is eligible for double digit royalties on net sales and \$145 million in milestone payments and tiered royalties for additional programs; 4. Poseida also received a US\$25m equity investment from Astellas; 5. Arcellx also received a US\$100m equity investment from Gilead

A differentiated position

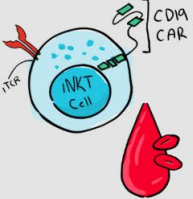

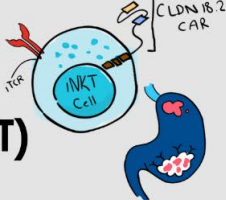

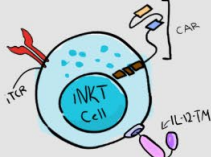

T cell and NK cell sectors are competitive



Companies with T cell, NK cell, or iNKT cell therapy programs.
Source: Company analysis based on public information

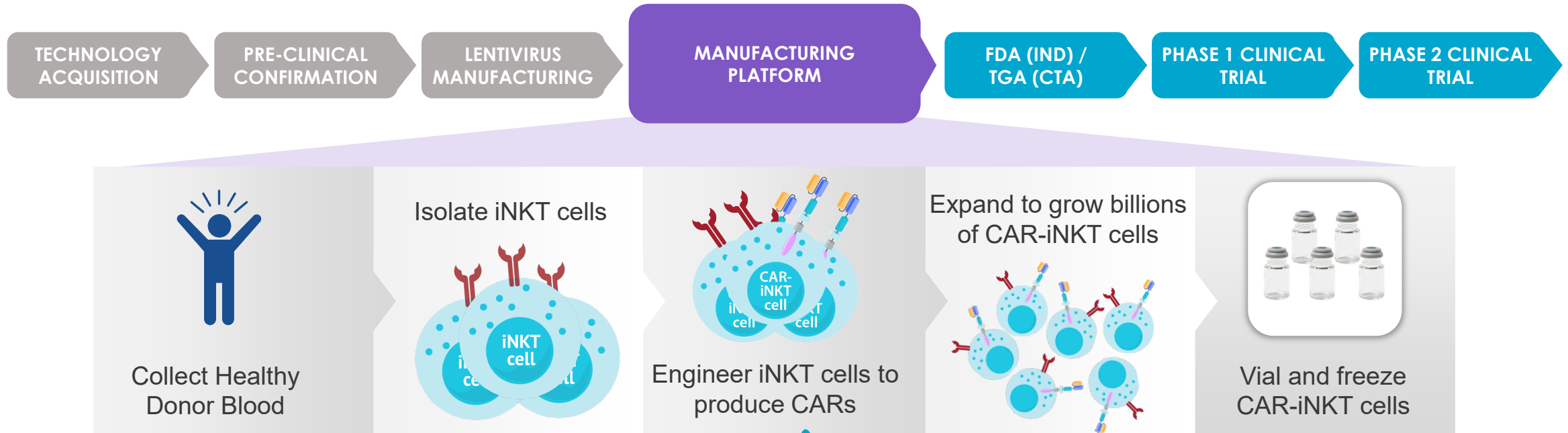
Arovella's expanding pipeline



| PRODUCT | INDICATION | DISCOVERY | PRECLINICAL | PHASE 1 |
|---|--|--|-------------|---------|
| <p>ALA-101 (CAR19-iNKT)</p>  | <p>CD19-positive cancers</p> |  | | |
| <p>ALA-105 (CLDN18.2-iNKT)</p>  | <p>CLDN18.2 positive solid tumours</p> |  | | |
| <p>IL-12-TM</p>  | <p>Solid Tumours</p> |  | | |

Clinic-ready manufacturing process developed for ALA-101

Semi-automated process suitable for large-scale and late-phase clinical development



Completed process development with excellent results:

- **High yield**, >5,000-fold expansion of CAR-iNKT cells
- **>60% of the cells have the CAR** (i.e. CAR-iNKT cells)
- **>99% purity** of iNKT cells
- **Maintains healthy balance** of CD4- and CD4+ cells
- **Semi-automated**, suitable for **large-scale production**
- Potential to leverage **FDA Platform Designation**

Successful pre-IND meeting with FDA

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

First formal interaction with FDA

Included a review of:

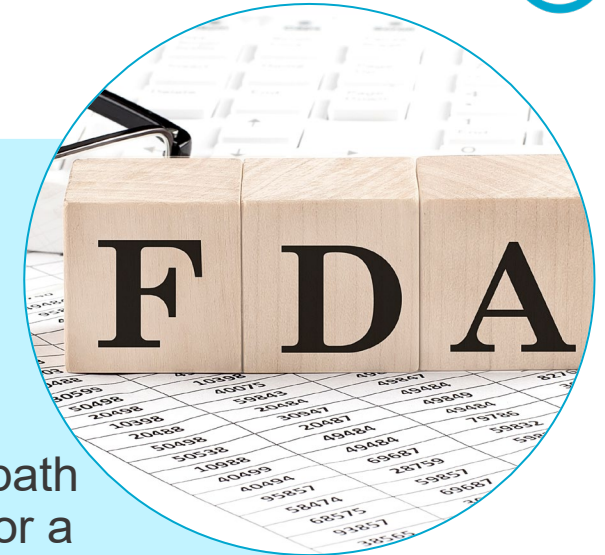
- Chemistry, Manufacturing and Controls (CMC) data
- Plan for non-clinical safety and efficacy studies
- Proposed phase 1 trial design



Positive feedback and clear path forward to submitting an IND for a phase 1 first-in-human clinical trial for ALA-101

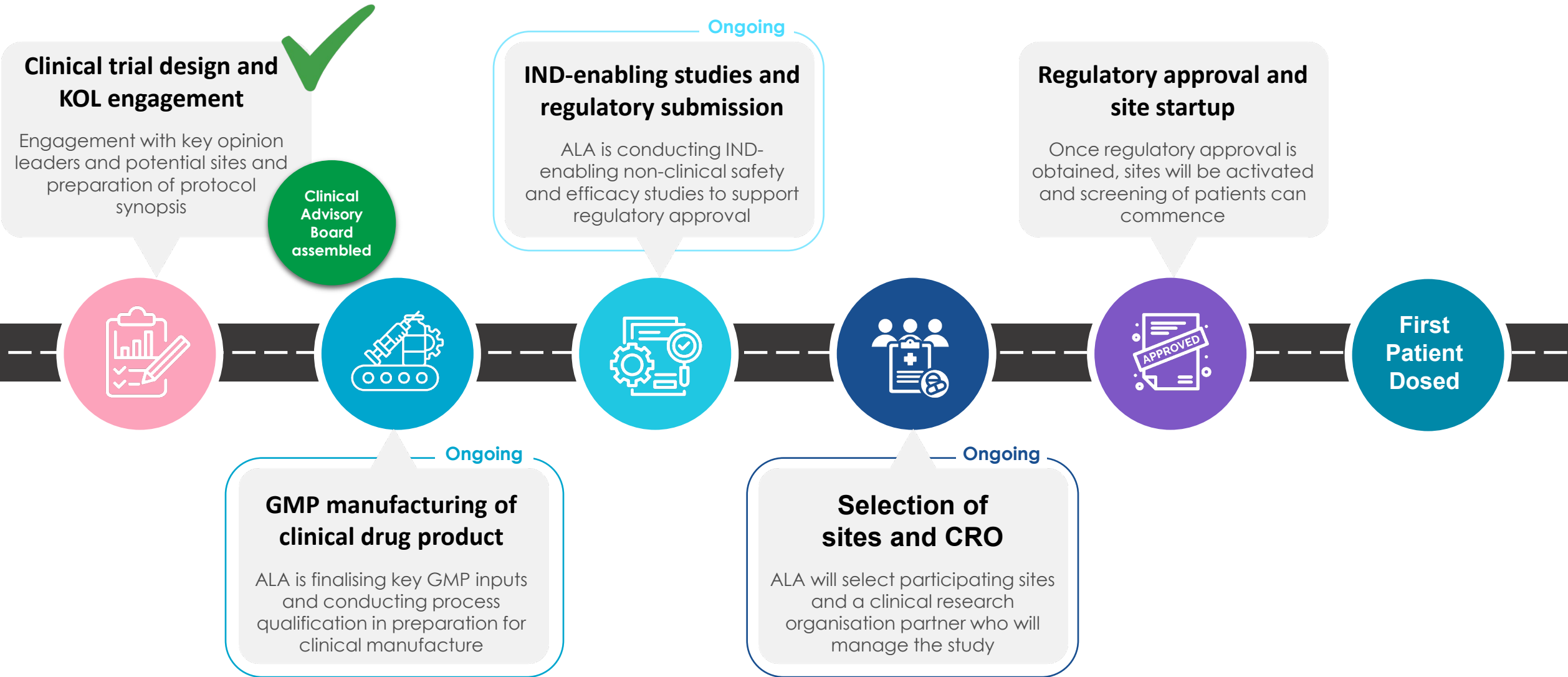


No major changes to the development plan proposed by ALA



Taking ALA-101 into first-in-human trials

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



Introducing Arovella's Clinical Advisory Board (CAB)

World class medical oncologists with early phase clinical trial expertise



Dr Salvatore (Sam) Fiorenza
Epworth HealthCare, Melbourne
Australia

- Dr Fiorenza (MBBS, PhD, BSc (Hons), MPH, FRACP, FRCPA) is a Consultant Haematologist, Deputy Director and Medical Lead of Cellular Therapies at Epworth Healthcare, Melbourne.
- Dr Fiorenza is recognised for his expertise in the development and application of CAR-T cell therapies.



Dr Debora Barton
ANIM8 LLC

- Dr Barton, MD, is a highly regarded oncologist with a significant focus on cell therapies.
- Dr Barton has extensive experience designing and running clinical trials from first-in-human phase 1 through to phase 3 and has accomplished regulatory designations and approvals for new oncology therapeutic products.



Professor Sattva Neelapu
The University of Texas MD Anderson
Cancer Center, Texas, USA

- Dr Neelapu, MD, is a Professor and Deputy Chair in the Department of Lymphoma and Myeloma at The University of Texas MD Anderson Cancer Center, Houston, Texas, USA.
- Dr Neelapu is internationally recognised for his pioneering contributions to the development of immunotherapies for blood cancers, particularly in CAR-T therapies.

ALA-101-001: phase 1 first-in-human study

Dose escalation and dose expansion study in patients with CD19+ blood cancers

Patients with relapsed or refractory CD19+ non-Hodgkin's lymphoma (NHL, including DLBCL, FL, MCL, MZL) and CD19+ leukemias (including B-ALL, CLL and HCL).

- Single dose of ALA-101 following lymphodepletion regimen
- **Primary objectives**
 - To evaluate the safety and tolerability of ALA-101 in adult patients with CD19+ NHL or leukemia
- **Secondary objectives**
 - To determine the most appropriate dose of ALA-101 for phase 2 clinical trials for adult patients with CD19+ NHL or leukemia
 - To evaluate the preliminary efficacy of ALA-101
 - To characterise the pharmacokinetic (PK) profile of ALA-101

Part 1: Dose Escalation

- 4 dose levels
- ~9-12 patients in total
- CD19+ NHL and leukemias

Part 2 (phase 1b): Dose Expansion

- Dose level selected from Part 1
- ~20 patients
- Sub-indications selected from Part 1

iNKT cells to target solid tumours

Arovella is implementing its strategy to target and kill solid tumours – 90% of newly diagnosed cancer cases¹



1. <https://www.cancer.gov/types/common-cancers>

Arovella's strategies to combat solid tumours

Arovella is using three approaches to expand the iNKT cell platform into solid tumours



License novel cancer targets

Identify and license new targets that are expressed in multiple cancers to incorporate into Arovella's iNKT cell therapy platform



Armour iNKT cells

Enhance the performance of iNKT cells by equipping iNKT cells with novel armouring technologies



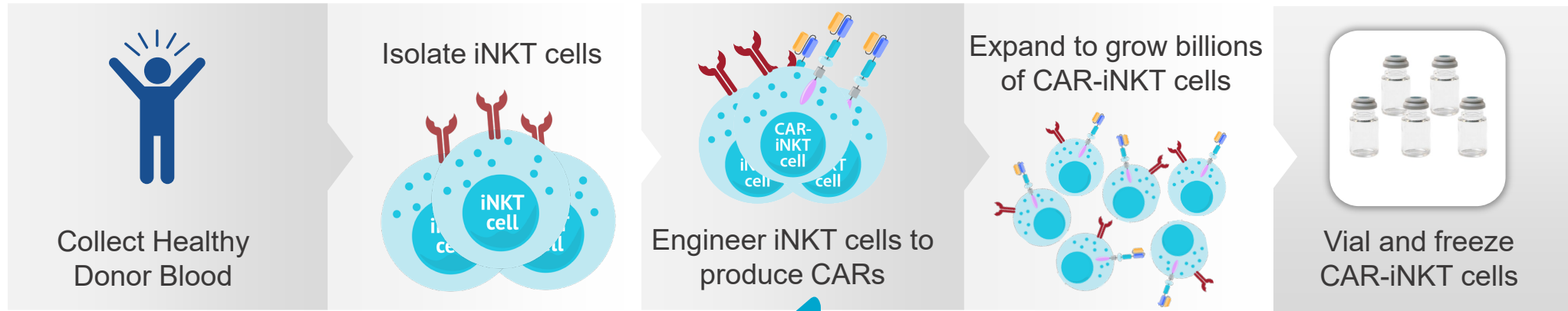
Create unique partnerships

Create partnerships to use novel combination therapies with synergistic effects

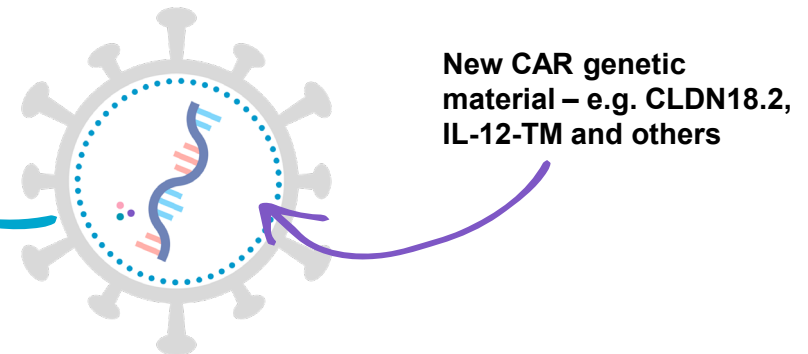
Add additional CARs for novel targets

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** cell products to target multiple cancer types



+ New lentivirus generated for each new CAR

Introducing Claudin 18.2 (CLDN18.2)

A promising solid tumour target

CLDN18.2 overexpression has been **identified in several types of cancers**

gastric cancer (GC)

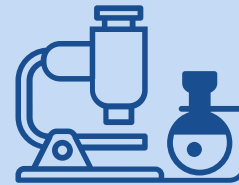
gastroesophageal junction cancer (GEJC)

pancreatic cancer (PC)

esophageal cancer (EC)

ovarian adenocarcinoma (OAC)

lung cancers (LC)



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

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

“Armouring” CAR-iNKT cells

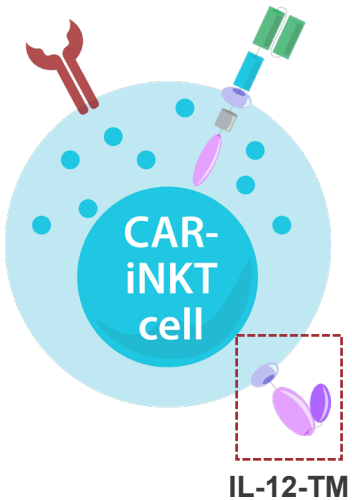
IL-12-TM (cytokine technology) enhances CAR-iNKT cell activity in solid tumours

IL-12-TM

IL-12-TM is a modified version of IL-12

with a membrane anchor that links it to the surface of CAR-iNKT cells. By linking it to the surface of iNKT cells, it can enhance CAR-iNKT cells without being released into the blood stream, making it safer.

The IL-12-TM is incorporated into the lentiviral vector and system and **does not require changes to the manufacturing process**



iNKT cells + IL-12-TM

Expand more and survive for longer
than CAR-iNKT cells lacking the cytokine

10x more circulating CAR-iNKT cells
4 weeks after treatment in a mouse model

Superior anti-tumour activity
compared to CAR-iNKT cells lacking the cytokine

The technology has been published in the prestigious, peer reviewed journal **Nature Communications**

[nature](#) > [nature communications](#) > [articles](#) > article

Article | [Open access](#) | [Published: 02 January 2024](#)

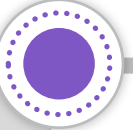
IL-12 reprograms CAR-expressing natural killer T cells to long-lived Th1-polarized cells with potent antitumor activity

Upcoming milestones for FY2025



July
2024

July
2025



ALA-101 (CD19)

- Complete cGMP manufacture for phase 1 and IND-enabling studies
- Complete preparatory activities for phase 1 study, preparation of regulatory dossier, engagement with clinical sites and KOLs
- Commence phase 1 dose escalation study for ALA-101 in patients with CD19+ NHL and leukemia



Arovella is funded to dose patients with ALA-101 during FY2025

ALA-105 (CLDN18.2)

- Proof-of-concept testing for CLDN18.2-iNKT cells and optimisation of the CAR construct for robust efficacy
- Generate animal data for CLDN18.2 targeting CAR-iNKT cells against gastric cancer and/or pancreatic cancer
- Commence activities to manufacture ALA-105 for clinic (e.g. lentiviral vector)

IL-12-TM Integration

- Integrate IL-12-TM into solid tumour programs and test its efficacy in anti-tumour models
- Enter into a Sponsored Research Agreement (SRA) with Professor Gianpietro Dotti's research group

Pipeline expansion

- Continue to identify and acquire novel technologies that enhance and expand Arovella's iNKT cell therapy platform

Summary



Novel allogeneic CAR-iNKT cell platform

iNKT cells serve as an excellent platform to develop allogeneic, or “off-the-shelf”, cell therapies to treat cancer



Lead product progressing to clinical trials

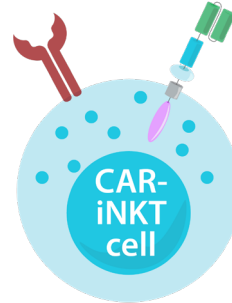
ALA-101, a potential treatment for CD19+ blood cancers, is being progressed to Phase 1 clinical trials, expected to commence in 2024

Improved manufacturing logistics

Allogeneic CAR-iNKT cells will significantly improve logistics and increase patient access



Arovella's CAR-iNKT Cell Platform



Arovella has an expanding pipeline

Arovella continues to expand its iNKT cell platform to potentially treat solid tumours

CAR-iNKT cells have multiple anticancer properties

CAR-iNKT cells have multiple anti-cancer properties that may support enhanced efficacy over other immune cell types



Arovella is poised for growth

Arovella's CAR-iNKT cell therapy platform is highly differentiated, and the Company has an expanding pipeline and a strong leadership team

ASX:ALA



Thank You

Dr. Michael Baker

CEO & Managing Director

Email: investor@arovella.com

Mobile: +61 403 468 187



Cell therapy deal references

1. <https://www.reuters.com/business/healthcare-pharmaceuticals/astrazeneca-signs-drug-development-deal-with-biotech-cellectis-2023-11-01/>
2. <https://www.businesswire.com/news/home/20230815091930/en/Precision-BioSciences-Completes-Strategic-Transaction-with-Imugene-for-Azer-Cel-in-Cancer>
3. <https://www.astellas.com/en/news/28271>
4. <https://www.jnj.com/janssen-enters-worldwide-collaboration-and-license-agreement-with-cellular-biomedicine-group-to-develop-next-generation-car-t-therapies>
5. <https://www.astrazeneca.com/media-centre/press-releases/2023/acquisition-of-neogene-therapeutics-completed.html>
6. <https://www.gilead.com/news-and-press/press-room/press-releases/2022/12/kite-and-arcellx-announce-strategic-collaboration-to-co-develop-and-co-commercialize-late-stage-clinical-cart-ddbcma-in-multiple-myeloma>
7. <https://www.fiercebiotech.com/biotech/genentech-pays-70m-access-arsenals-armoury-t-cell-tools-quest-solid-tumor-car-t>
8. <https://www.prnewswire.com/news-releases/poseida-therapeutics-announces-strategic-global-collaboration-with-roche-focused-on-allogeneic-car-t-cell-therapies-for-hematologic-malignancies-301598555.html>
9. <https://www.adaptimmune.com/investors-and-media/news-center/press-releases/detail/197/adaptimmune-enters-into-a-strategic-collaboration-with>
10. <https://www.gilead.com/news-and-press/press-room/press-releases/2021/8/kite-and-appia-bio-announce-collaboration-to-research-and-develop-allogeneic-cell-therapies-for-cancer>
11. [https://www.nasdaq.com/articles/athenex-snaps-up-kuur-therapeutics-for-\\$185m-street-sees-133.7-upside-2021-05-05](https://www.nasdaq.com/articles/athenex-snaps-up-kuur-therapeutics-for-$185m-street-sees-133.7-upside-2021-05-05)
12. <https://eternatx.com/news/brooklyn-immunotherapeutics-completes-acquisition-of-eterna-therapeutics/>
13. <https://www.astellas.com/en/news/15516>

ASX:ALA



Thank You

Email: investor@arovella.com
Mobile: +61 403 468 187

