ASX:**ALA**

arovella THERAPEUTICS

Completion of $12.5m Placement

March

2024

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Summary

TOPIC	DISCUSSION
Arovella Summary	• Arovella is now funded to see data from its Phase 1 Clinical Trial • Developing unique, proprietary, allogeneic cell therapy treatments for cancers using novel iNKT cell platform (CAR-iNKT) • Lead product is ALA-101 (CAR19-iNKT), a potential new treatment for CD19-expressing blood cancers including Non-Hodgkin's lymphomas and leukaemias • Demonstrated superior efficacy for ALA-101 relative to CAR-T cells in *in vitro* and *in vivo* models • Demonstrated ability to generate large numbers of highly cytotoxic cells from healthy donor starting material, providing for production of multiple doses from a single manufacturing batch, leading to a truly 'off-the-shelf' cell therapy. • Phase 1 first-in-human study planned for 2024 • Several strategies developed to use CAR-iNKT cells to treat solid tumours

Capital Raising to advance ALA-101 to clinical trials	• Arovella has raised $12.5m to advance its lead product, ALA-101, into phase 1 first-in-human clinical trials.
	• Specifically, funds raised will be used to:
	  • Complete GMP manufacture of ALA-101 for phase 1
	  • Complete IND-enabling non-clinical safety and efficacy studies to support a phase 1 study in CD19+ B cell malignancies
	  • Commence and advance phase 1 clinical trial for ALA-101 and generate human data
	  • Continue development of additional pipeline products including ALA-105, IL-12-TM and future partnerships

Offer Details	• $12.5 million Placement ("Placement"). • The Offer was priced at $0.10 per New Share ("Offer Price"), which represents a: • 23.1% discount to last close on 21 March 2024 • The Offer includes a 1-for-1 attaching Option with an exercise price of $0.15 and an expiry date of 3 years from date of issue. • As at 31 December 2023, Arovella had net cash of $4.8 million. Post the offer, the Company will have a pro-forma cash balance (net of offer costs) of approximately $16.5 million. The Company also expects an R&D Tax Incentive receivable for FY24 of ~$3.5 million to be received in Q4 2024.

Arovella's strengths

Off-the-Shelf iNKT Cell Platform

Developing off-the-shelf iNKT cell therapies to target blood cancers and solid tumour cancers

Funded to take ALA-101 into Phase 1

ALA-101, a potential treatment for CD19-expressing blood cancers, is funded to progress to Phase 1 clinical trials, expected to commence in 2024

Addressing Key Unmet Need

Our iNKT cell platform is well positioned to solve key challenges that hamper the cell therapy sector

Strong Leadership Group

Leadership team and Board have proven experience in drug development, particularly cell therapies

Strategic Acquisitions

Focused on acquiring innovative technologies that strengthen its cell therapy platform and align with its focus areas

Unique Value Proposition

Arovella is among few companies globally developing an iNKT cell therapy platform

Financial overview

Financial Snapshot

ASX CODE	ALA
Market capitalisation[1]	$120.3 million
Shares on issue	925.16 million
52-week low / high[1]	$0.033 / $0.185
Cash Balance (Dec 31 2023)	$4.76 million

Major Shareholders

Shareholder	Ownership (%) [1]
THE TRUST COMPANY (AUSTRALIA) LIMITED	56,231,926 (6.11%)
RICHARD JOHN MANN	50,905,657 (5.53%)
UBS NOMINEES PTY LTD	20,620,196 (2.24%)
BLACKBURNE CAPITAL PTY LTD	18,717,456 (2.03%)
DYLIDE PTY LTD	15,666,666 (1.70%)

1. *As of 21 March 2024*

Recent cell therapy transactions[1]

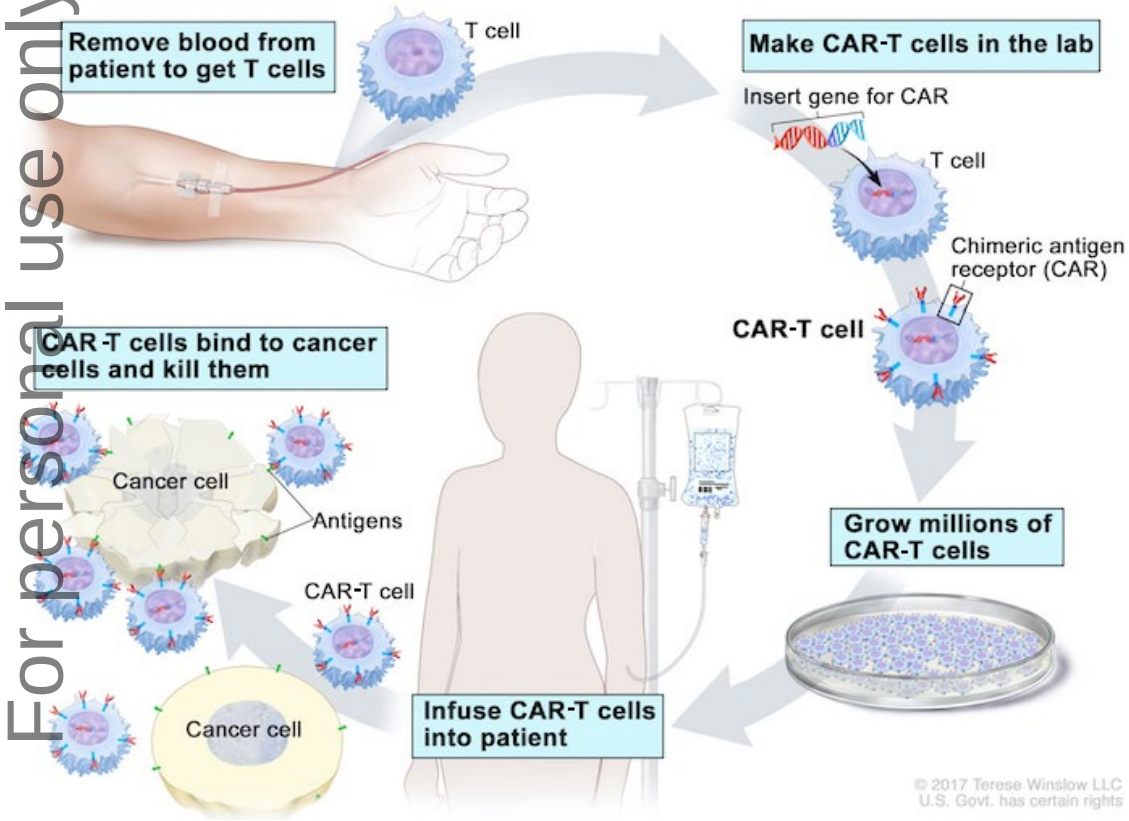
Date	Type of deal	Acquirer/Licensee	Target/Licensor	Cell Type	Stage	Upfront (US$M)	Milestones (US$M)	Total deal value (US$M)
Dec-23	Acquisition	AstraZeneca	GRACELL	T Cell	Phase 1b	$1,000	$200	$1,200
Nov-23	Collaboration and investment[2]	AstraZeneca	cellectis	Not specified	Platform	$25	$70-220 per product	
Aug-23	Licence[3]	IMUGENE Developing Cancer Immunotherapies	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 Cellular Biomedicine Group	T Cell	Phase 1b	$245	*undisclosed*	
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	*undisclosed*	
Sep-22	Research collaboration	Genentech A Member of the Roche Group	ArsenalBio	T Cell	Preclinical	$70	*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	Adaptimmune	T Cell	Preclinical	$150	$150	$300
Aug-21	Research collaboration	GILEAD	APPIA BIO	iNKT Cell	Preclinical	*undisclosed*	*undisclosed*	$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*

About CAR-T cells

How original CAR-T cell therapies work

CAR-T cell therapy is personalised medicine



T cells = immune cell

T cells are a common type of immune cell that fight infections and can help fight cancer.

T cells from patient 'reprogrammed'

To generate autologous CAR-T cells, T cells are taken from a patient with blood cancer and 'reprogrammed' to produce a Chimeric Antigen Receptor (CAR). The CAR can recognise cancer cells through a target antigen.

CAR-T cells find & kill tumour cells

CAR-T cells are administered to the patient to find and kill the tumour cells. Once the CAR binds to a tumour cell, the CAR-T cell is activated to kill the tumour cell.

https://www.ohsu.edu/sites/default/files/2021-04/CAR%20TcellTherapy7-700px.jpg

Cell Therapy has revolutionised blood cancer treatment

CAR-T cells have demonstrated their curative potential in blood cancers

The Cell Therapy market is expected to reach

$61.2 billion

by 2030[1]

Cure

CAR-T cells have demonstrated ability to **cure haematological cancers**

Strong Sales

40-60%

Patients relapse post-CAR-T therapy[2]

Product	Approval Year	2023 Revenue
YESCARTA (axicabtagene ciloleucel)	2017	US$1498m[3]
KYMRIAH (tisagenlecleucel)	2017	US$509m[4]
Abecma (idecabtagene vicleucel)	2021	US$472m[5]

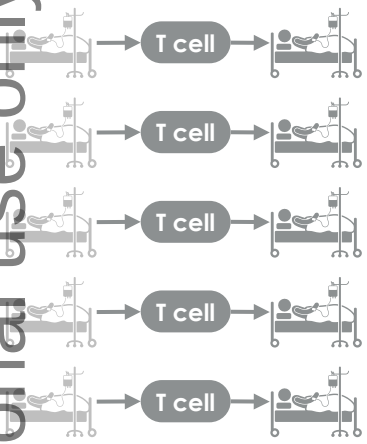
1. *https://www.businesswire.com/news/home/20230529005130/en/Global-Cell-Therapy-Market-Report-2023-Advancements-in-Biotechnology-Drives-Growth---ResearchAndMarkets.com*
2. *Zinzi et al., 2023 Pharmacological Research - 10.1016/j.phrs.2023.106742*
3. *https://www.gilead.com/news-and-press/press-room/press-releases/2024/2/gilead-sciences-announces-fourth-quarter-and-full-year-2023-financial-results#:~:text=Yescarta%C2%AE%20(axicabtagene%20ciloleucel)%20sales,%E2%80%9D)%20outside%20the%20United%20States.*
4. *https://www.novartis.com/sites/novartis_com/files/2024-01-interim-financial-report-en.pdf*
5. *https://news.bms.com/news/details/2024/Bristol-Myers-Squibb-Reports-Fourth-Quarter-and-Full-Year-Financial-Results-for-2023/default.aspx*

Emily Whitehead - **Celebrating 10 years of CAR-T cell therapy**

https://emilywhiteheadfoundation.org/10-years-of-car-t/

Autologous CAR-T pose challenges

The current manufacturing costs and time are limiting



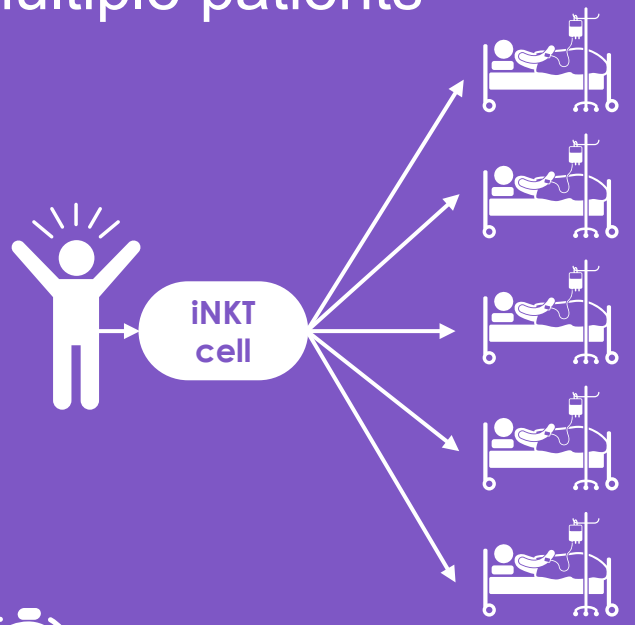
Each manufacturing batch is **patient-specific**

Patient must wait **3-4 weeks** for therapy

- Manufacturing & supply chain **costs are high**
- T cells **can be compromised** due to disease
- **Limited centres** can collect and manufacture
- **Time is an issue** for patients with aggressive disease
- Manufacturing run **failures can occur**

Allogeneic

A single healthy donor batch = treatment for multiple patients

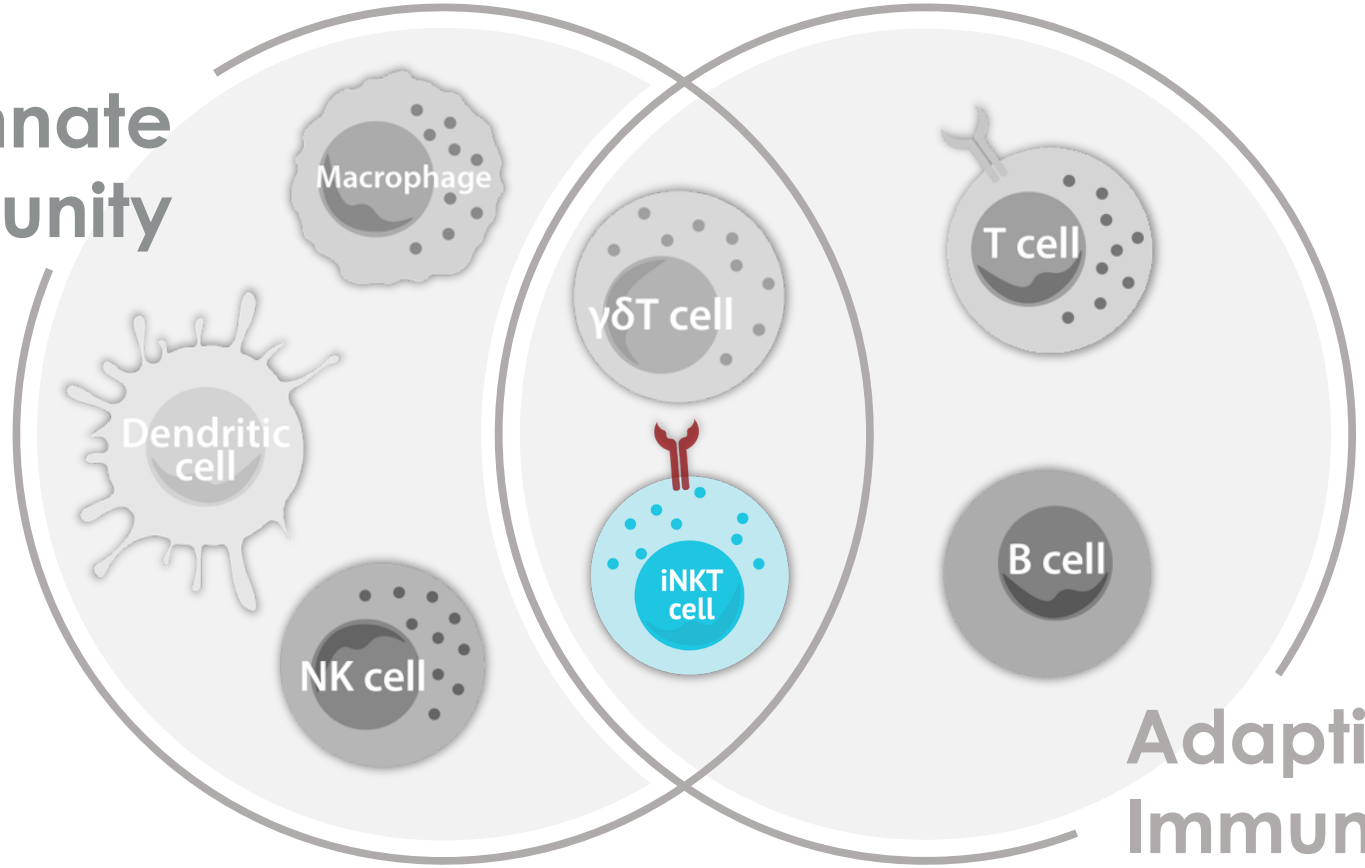


1 week

Patients ready to dose within 1 week

iNKT cells represent a next-generation cell therapy

Properties make them ideal for use in cell therapy



Strong safety profile

- Don't cause graft versus host disease (GvHD)

Front line of the human immune system

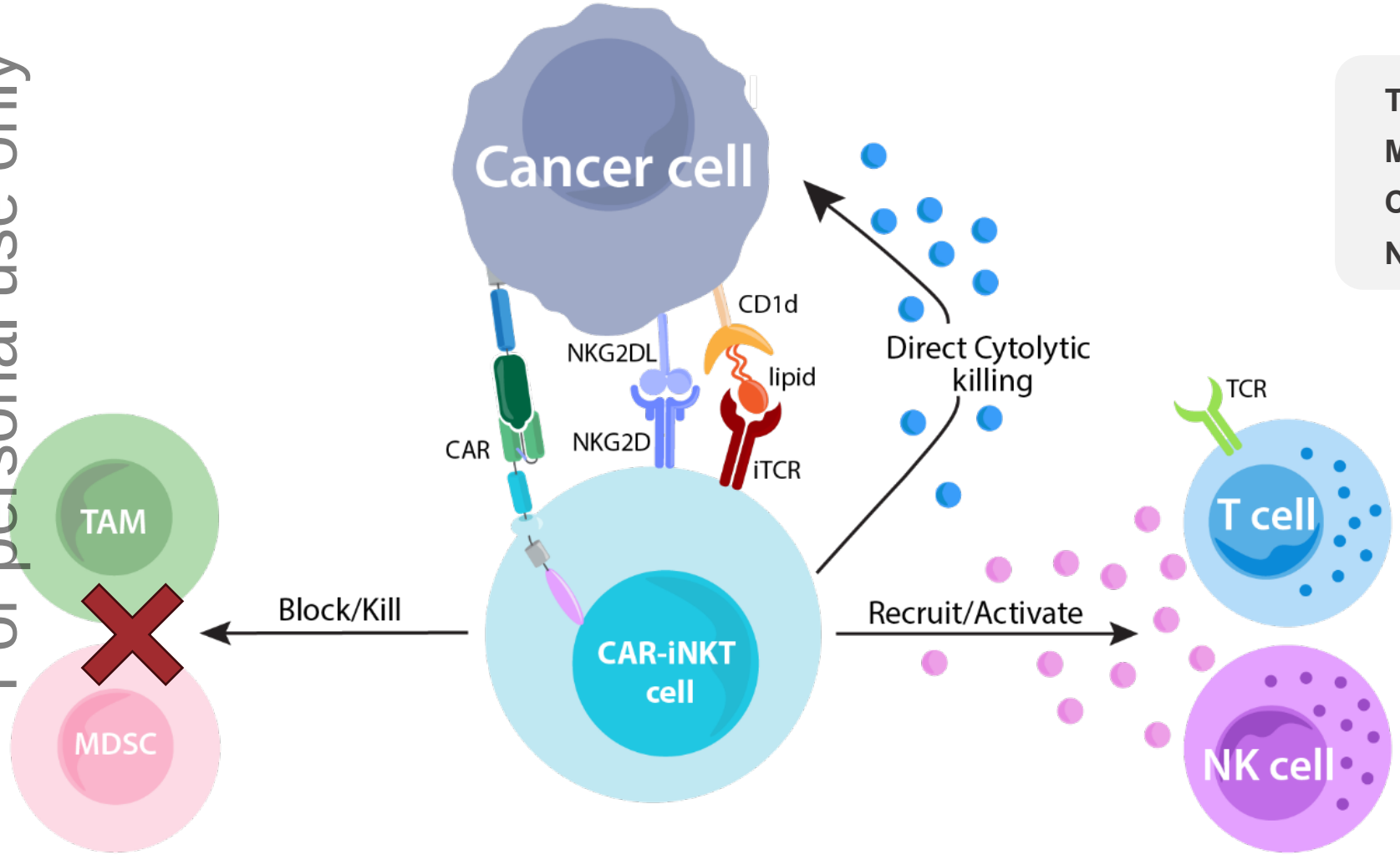
- Bridge innate & adaptive immune responses
- Contain both T cell & NK cell killing mechanisms
- Naturally target & kill cancers that express CD1d

Multiple anti-cancer properties

- Shape the tumour microenvironment by blocking/killing pro tumour cells (TAMs/MDSCs)
- Infiltrate tumours & secrete signaling molecules to activate other immune cells to kill tumour cells

CAR-iNKT cells have multiple ways to kill cancer cells

Also recruit 'good' immune cells and block 'bad' immune cells

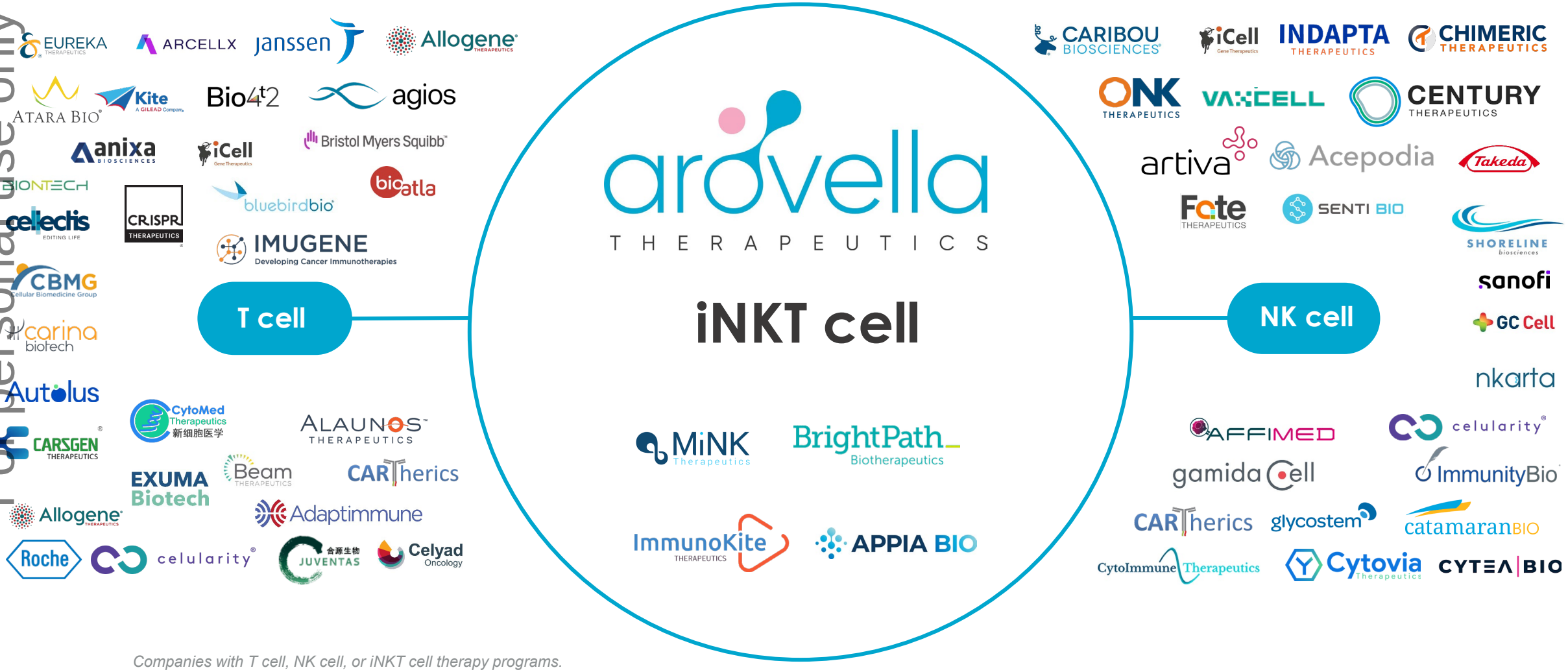


TAM	Tumour Associated Macrophage
MDSC	Myeloid Derived Suppressor Cell
CAR	Chimeric Antigen Receptor
NK	Natural Killer

1. **Via the CAR**
   - Specific target depending on tumour type
2. **Via the NKG2D pathway**
   - NKG2D ligands are upregulated in cancer cells
3. **Via lipid-bound CD1d**
   - Several cancers naturally express CD1d

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

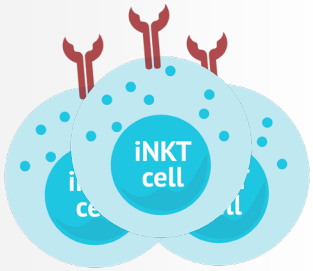
CAR-iNKT cell therapy production advantages

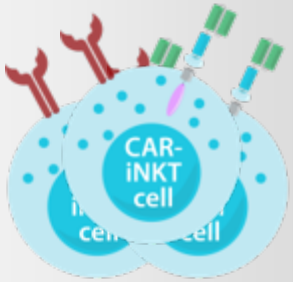
Off-the-shelf manufacturing advantages

MANUFACTURING

Collect Healthy Donor Blood

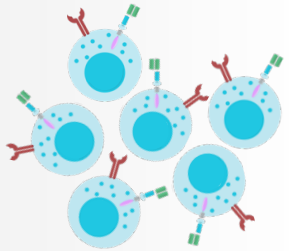
Isolate iNKT cells





Engineer iNKT cells to produce a CAR

Expand to grow billions of CAR-iNKT cells

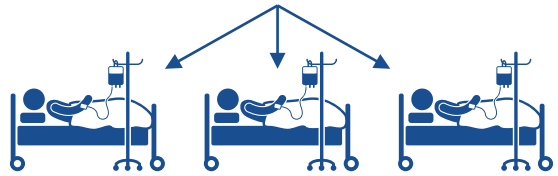


Vial and freeze CAR-iNKT cells

TREATMENT

Thaw CAR-iNKT cells

Dose eligible patients



Healthier starting material
Potentially better efficacy

Scalable manufacturing with reduced costs
Reach more patients

Faster access to treatment
Improved outcomes for aggressive cancers

Removes risk of manufacturing run failure

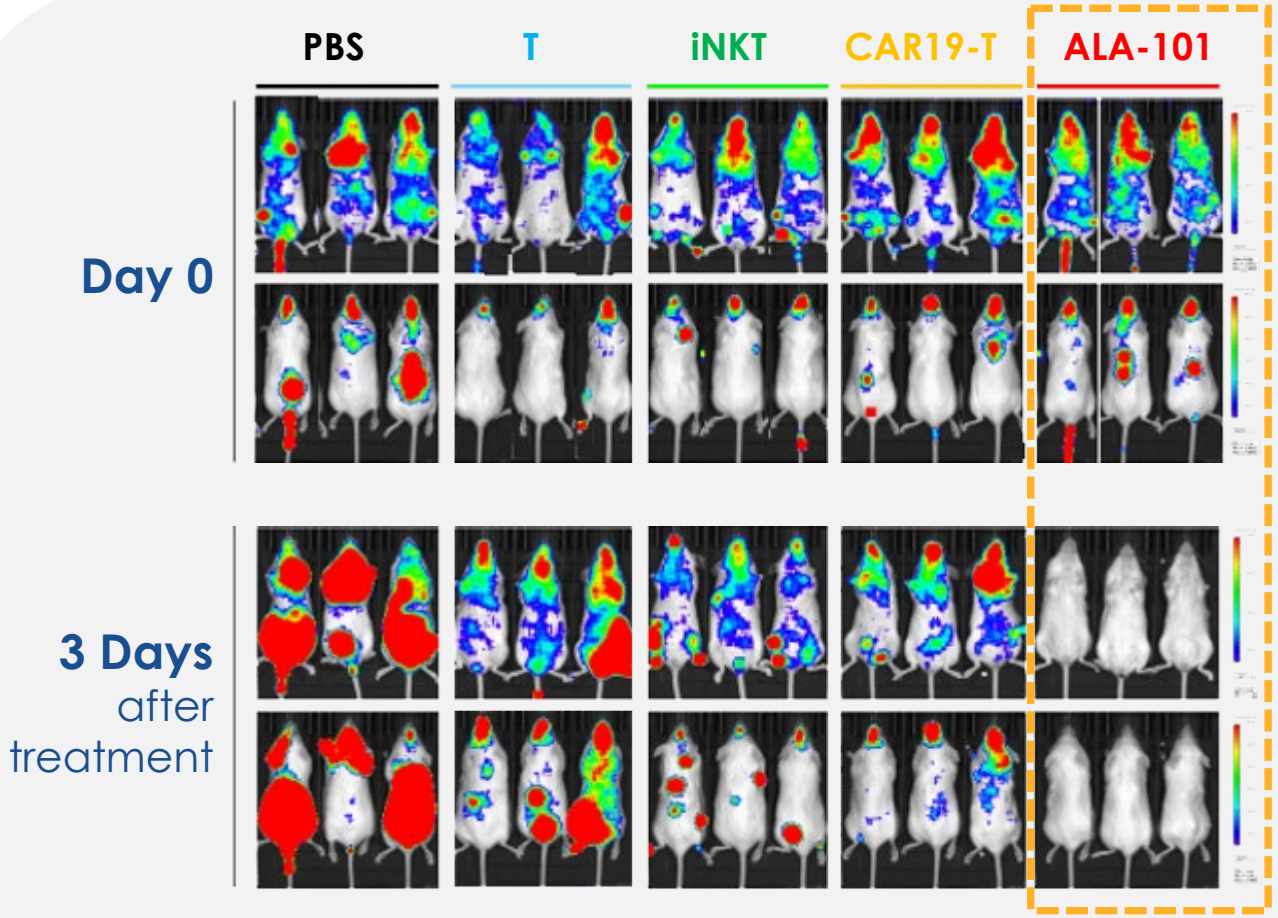
ALA-101 (CAR19-iNKT cells)

A next generation **off-the-shelf** cell therapy for CD19 expressing cancers

ALA-101: enhanced tumour killing *in vivo*

ALA-101 rapidly eradicates tumour cells in mice

- Tumour cells expressing **CD19** and **CD1d** were intravenously delivered into mice
- Mice were treated with:
  - PBS (saline)
  - Unmodified T cells (T)
  - Unmodified iNKT cells (iNKT)
  - CAR19-T cells
  - ALA-101 (CAR19-iNKT cells)
- After three days, ALA-101 resulted in significant regression of tumour cells
- In all other treatments, there was strong tumour cell persistence
- ALA-101 displays swift action

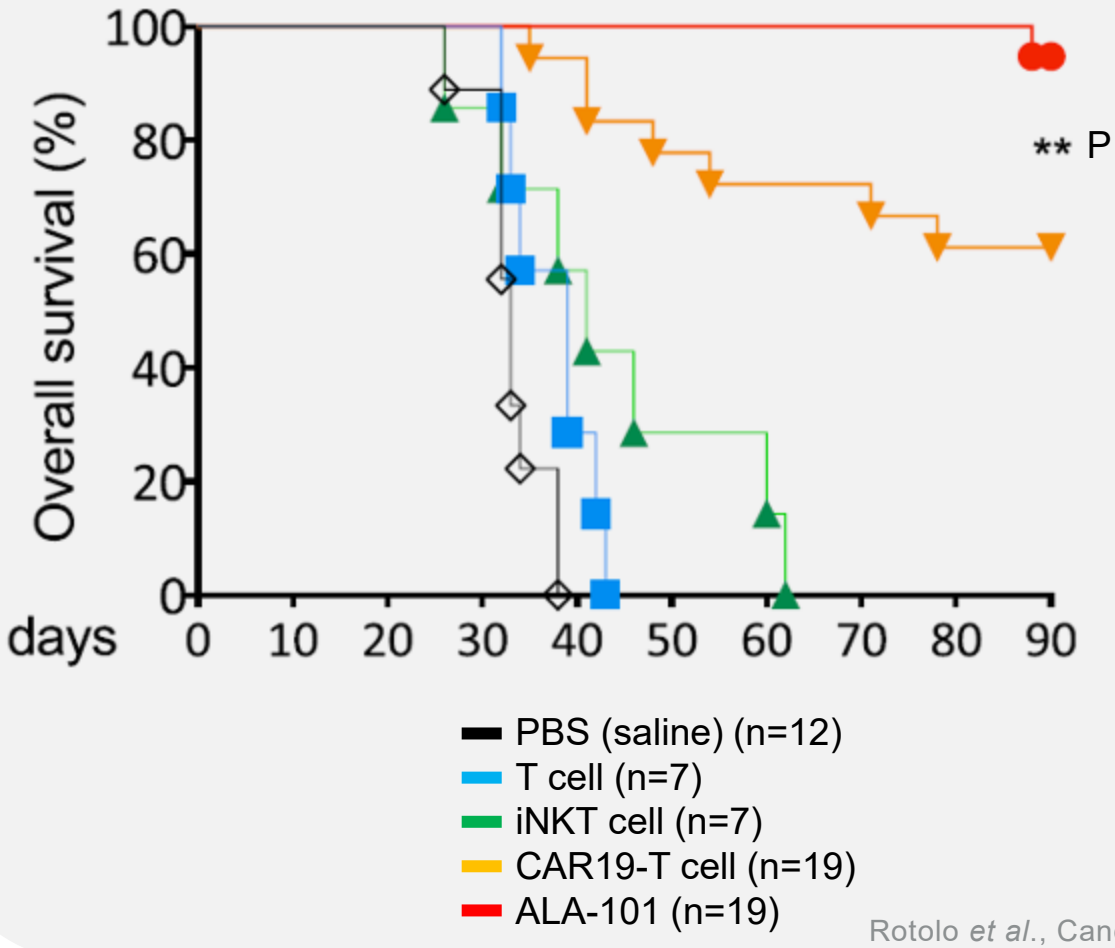


Rotolo *et al.*, Cancer Cell (2018)

ALA-101: next generation cell therapy

ALA-101 significantly increased survival in mice versus treatment with CAR19-T cells

- Tumour cells expressing **CD19** and **CD1d** were intravenously delivered into mice
- Mice were treated with:
  - PBS (saline)
  - Unmodified T cells (T)
  - Unmodified iNKT cells (iNKT)
  - CAR19-T cells
  - ALA-101 (CAR19-iNKT cells)
- After 90 days, only mice treated with CAR19-T cells or ALA-101 remained alive
- 1.5x more mice treated with ALA-101 remained alive after 90 days relative to CAR19-T cells
- ALA-101 has the potential to be an effective, off-the-shelf cell therapy for the treatment of CD19-expressing cancers

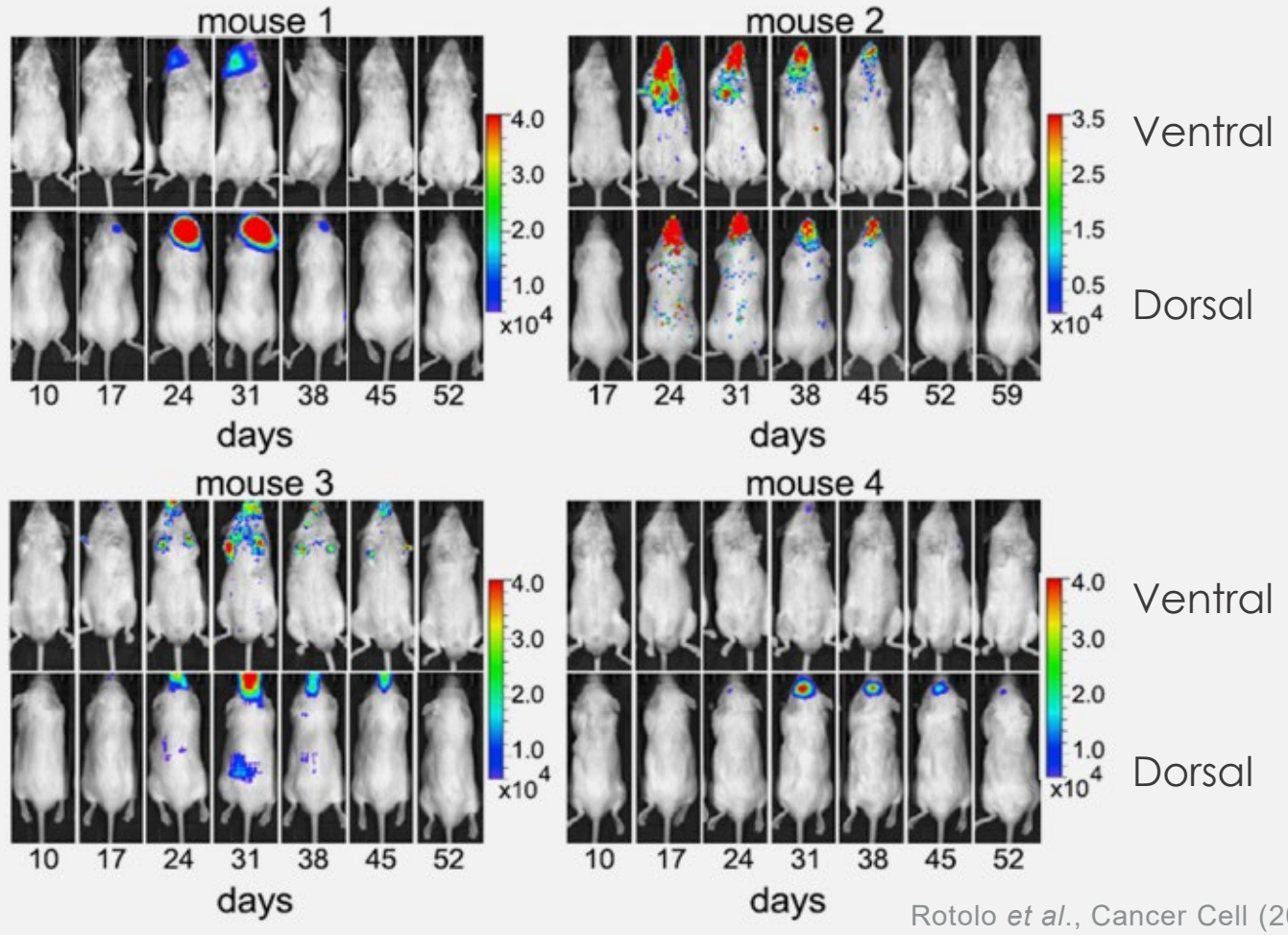


Rotolo *et al.*, Cancer Cell (2018)

ALA-101: spontaneous secondary remission

ALA-101 activity may persist to eradicate tumour cells following relapse

- Four mice treated with ALA-101 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
- Potential to use ALA-101 to treat central nervous system lymphoma or brain metastases



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

Progress towards first-in-human clinical trials

ALA-101 data confirms activity and off-the-shelf capability

Potent antitumour activity

Demonstrated efficacy of ALA-101 against CD19+ lymphomas and leukemias. Proof-of-concept data with clinical-designed lentiviral vector in animal models using thawed, “off-the-shelf” ALA-101.

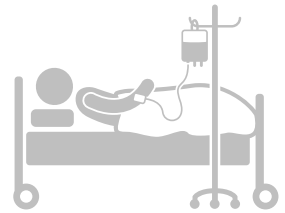
Expected to be safe

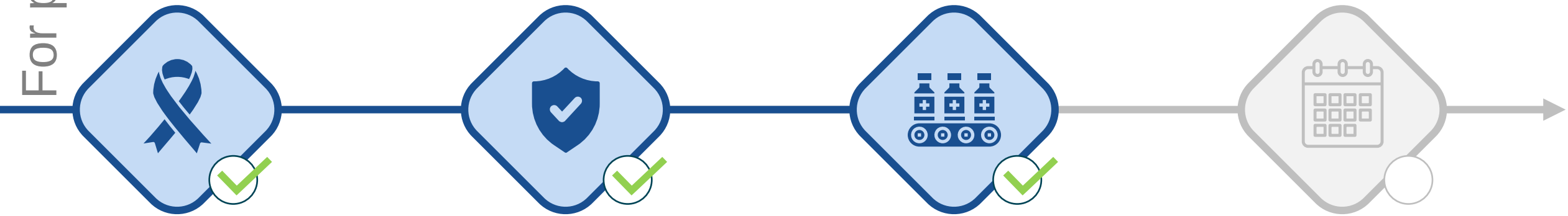
iNKT cells have been shown in clinical trials not to cause graft versus host disease (GvHD) and the CD19 targeting CAR (FMC63) is a validated targeting agent in approved cell therapies.

Multiple dose manufacturing

ALA has demonstrated that its manufacturing process can produce a high number of CAR+ cells with potent cell killing properties and has completed production of GMP-grade lentivirus for CD19 CAR expression.

Phase 1 clinical trial anticipated CY 2024





iNKT cells to target solid tumours

Arovella is implementing its strategy to target and kill solid tumours – 90% of newly diagnosed cancer cases[1]

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

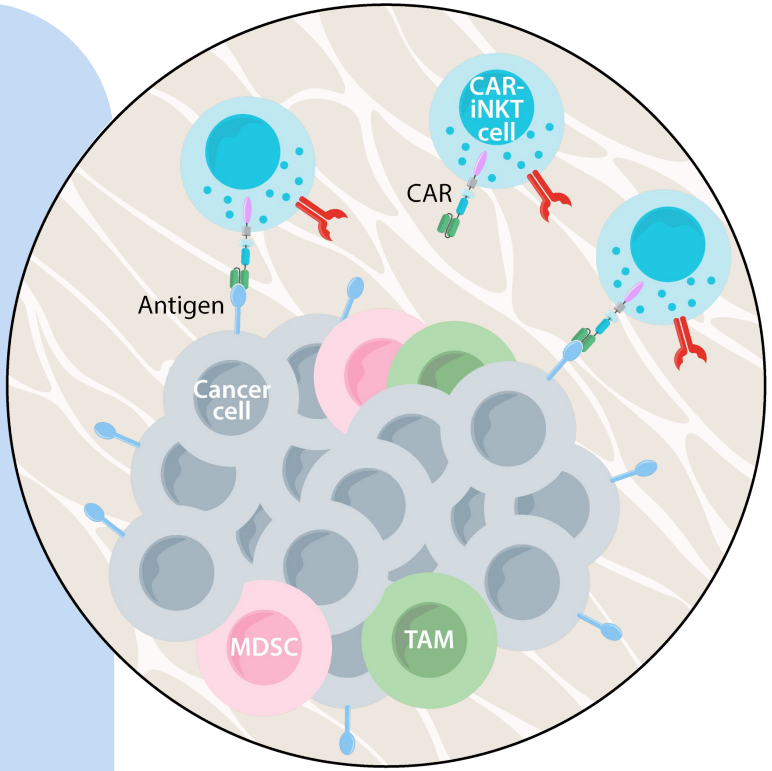
Create partnerships to use novel combination therapies with synergistic effects

Solid tumours pose challenges to cell therapies

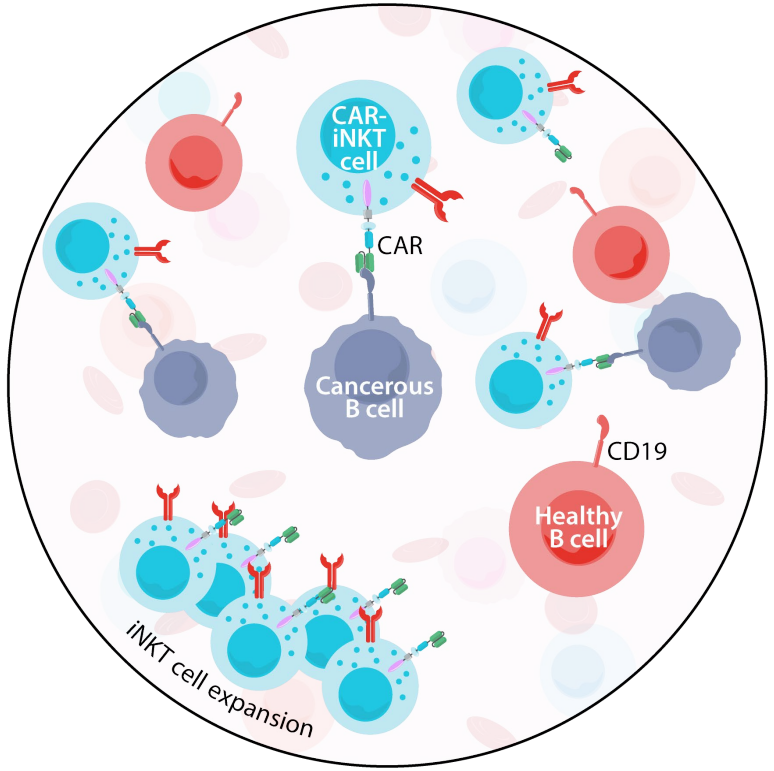
Solid tumours are more

difficult to treat with cell therapies

- Access to tumour
- Antigen specificity and uniformity
- Tumour microenvironment contains cells that support cancer cell growth



Solid tumour



Blood cancer

iNKT cells:

- Home to tissues and infiltrate tumours
- Modify the TME to block or kill cells that promote tumour growth and recruit helpful immune cells

TAM = Tumour Associated Macrophage; MDSC = Myeloid Derived Suppressor Cell; CAR = Chimeric Antigen Receptor

Add additional CARs for novel targets

STRATEGY 1

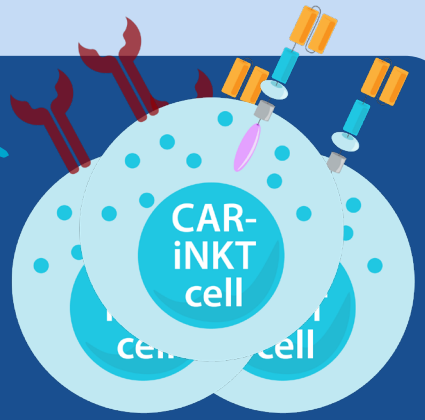
Arovella's manufacturing process can be leveraged for multiple cancer types

MANUFACTURING

CARs targeting novel antigens specific for solid tumours

can be incorporated into iNKT cells

using the same manufacturing process



New lentiviral vector generated for each new CAR

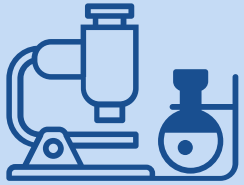
Introducing Claudin 18.2 (CLDN18.2)

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 expected to be **approved in 2024**

Gastric cancer

market alone expected to reach **$10.7 billion** by 2031[1]

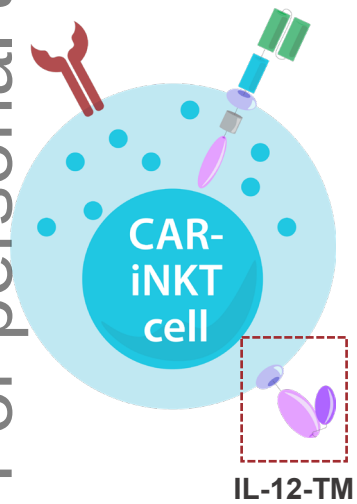
1. *https://www.alliedmarketresearch.com/gastric-cancer-market-A74458#:~:text=The%20global%20gastric%20cancer%20market,cells%20lining%20of%20the%20stomach*

“Armouring” CAR-iNKT cells

STRATEGY 2

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

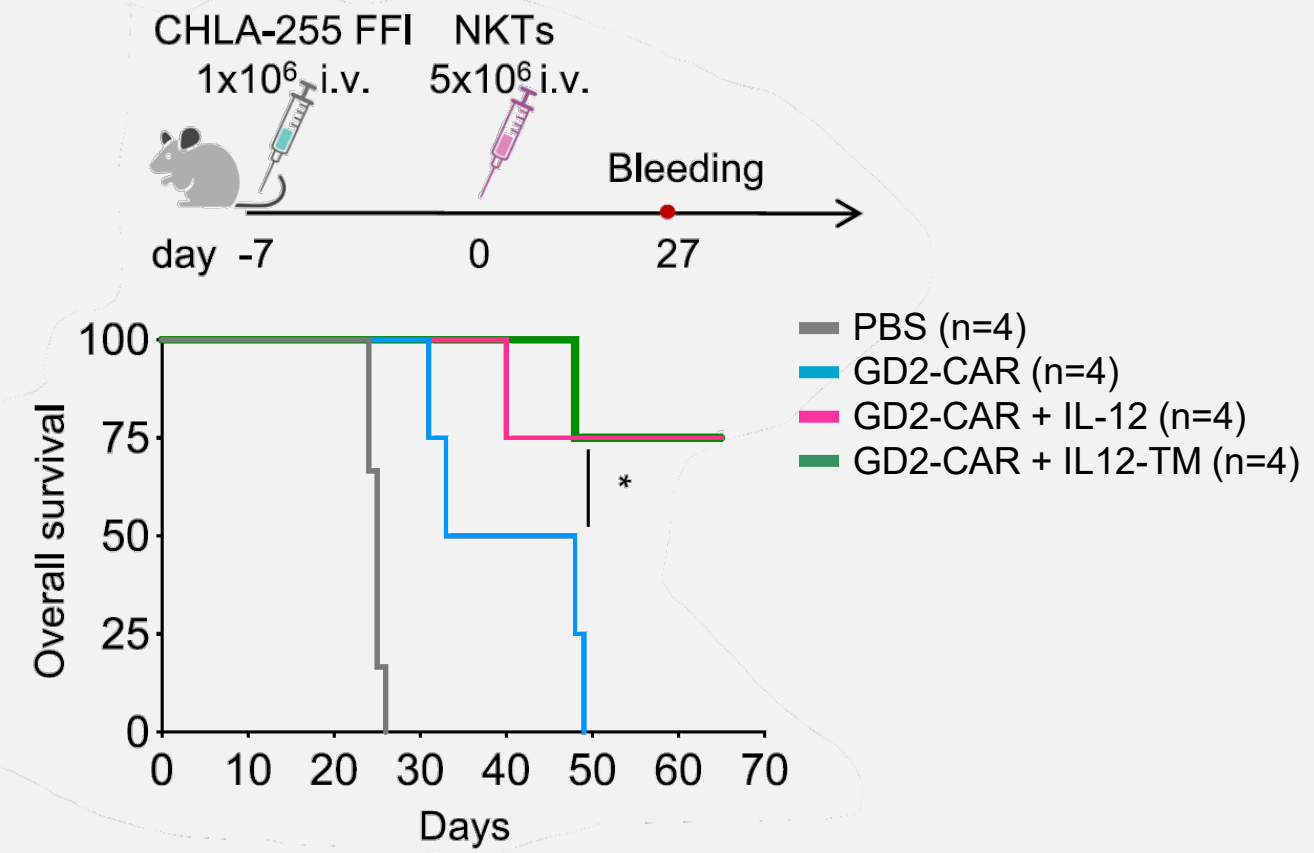
Article | Open access | Published: 02 January 2024

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

Key benefits of IL-12-TM for CAR-iNKT cells

IL-12-TM enhances antitumor activity of CAR-iNKT cells

- Tumour cells expressing GD2 and were intravenously delivered into mice before treatment with CAR-iNKT cells
- Mice were treated with:
  - PBS (saline)
  - GD2-CAR
  - GD2-CAR + IL-12
  - GD2-CAR + IL-12-TM
- After 60 days, only mice treated with GD2-CAR + IL12 or IL-12-TM remained alive
- IL-12-TM enhances CAR-iNKT cell numbers and antitumour activity



Landoni *et al.*, Nature Communications (2024)

Key benefits of IL-12-TM for CAR-iNKT cells

We expect IL-12-TM to enhance Arovella's CAR-iNKT cell platform

Increases CAR-iNKT cell numbers

IL-12-TM prolongs persistence of CAR-iNKT cells. Cells continue to proliferate and increase in number.

IL-12-TM is not released from CAR-iNKT cells

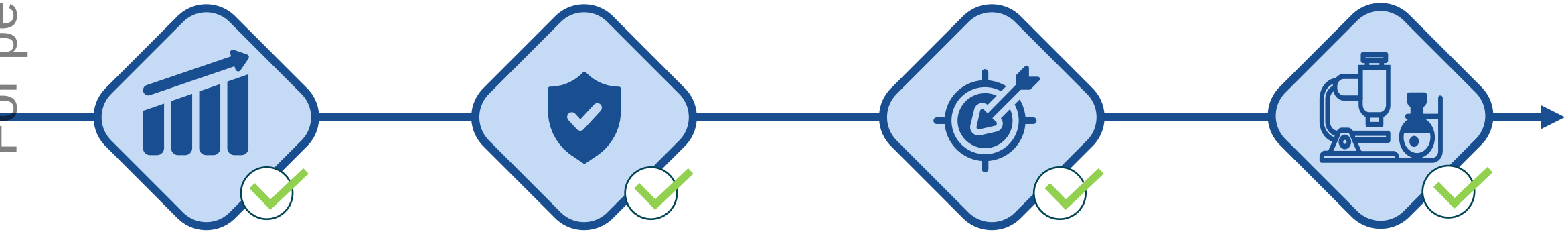
IL-12-TM is not released from CAR-iNKT cells and is expected to be safer than secreted IL-12.

Enhances CAR-iNKT cell antitumour activity

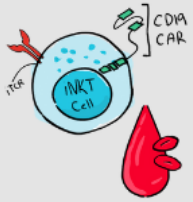
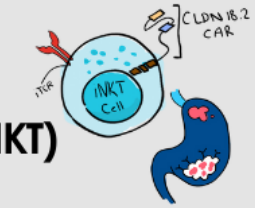
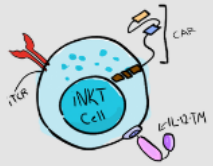
IL-12-TM enhances CAR-iNKT antitumor activity against solid tumour cancers like neuroblastoma

Integrates with existing manufacturing process

IL-12-TM incorporated into lentiviral vector and does not require changes to manufacturing process



Arovella's expanding pipeline

PRODUCT	INDICATION	DISCOVERY	PRECLINICAL	PHASE 1
ALA-101 (CAR19-iNKT) 	CD19 Expressing cancers	CD19 Expressing Lymphoma		
ALA-105 (CLDN18.2-iNKT) 	CLDN18.2 positive solid tumours	Gastric & Pancreatic Cancers		
IL-12-TM 	Solid Tumours	Solid Tumours		

Upcoming milestones for 2024

	January 2024	July 2024	December 2024
ALA-101 (CD19)	▪ Complete cGMP manufacture for Phase 1 clinical trials ▪ Complete preparatory activities for Phase 1 study, including preparation of regulatory dossier, engagement with clinical sites and KOLs	▪ Commence Phase 1 for ALA-101 targeting CD19+ lymphoma and leukemia	
ALA-105 (CLDN18.2)	▪ Initiate proof-of-concept testing for CLDN18.2-iNKT cells to expand iNKT platform for treatment of solid tumours ▪ Optimise 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		

Expect to advance ALA-101 to Phase 1 first-in-human clinical trial during 2024

Dose escalation Phase 1 study in patients with CD19+ blood cancers

cGMP – Current Good Manufacturing Practice; KOLs – key opinion leaders

Strong Leadership

Leadership

Dr. Michael Baker

CEO & MANAGING DIRECTOR

Dr. Nicole van der Weerden

CHIEF OPERATING OFFICER

Dr. Robson Dossa

VP MANUFACTURING & QUALITY

Dr. Simon Poon

DIRECTOR PROJECT MANAGEMENT

Board of Directors

Dr. Tom Duthy

BOARD CHAIR

Dr. Elizabeth Stoner

DIRECTOR

Dr. Debora Barton

DIRECTOR

Mr. Gary Phillips

DIRECTOR

Summary

Novel allogeneic CAR-iNKT cell platform

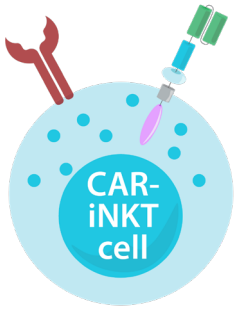
iNKT cells serve as an excellent platform to develop allogeneic, or “off-the-shelf”, cell therapies to treat cancer

Improved manufacturing logistics

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

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’s CAR-iNKT Cell Platform

Lead product progressing to clinical trials

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

Arovella has an expanding pipeline

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

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

Source and use of funds

Comments

- $12.5 million Placement
- With the proceeds of the capital raising, Arovella expects to have sufficient capital to:
  - manufacture cGMP drug product for clinical trials;
  - conduct IND-enabling safety and efficacy studies to support clinical trials;
  - initiate a phase 1 first-in-human clinical trial in Non-Hodgkin's Lymphoma;
  - continue development of additional pipeline products including ALA-105, IL-12-TM and future partnerships.
- Expenses are net of R&D Tax Incentive receivable

	$12.5M PLACEMENT	
Source of funds	**$ (millions)**	
Capital raised under the Offer	**12.5**	
Expected Use of funds	**$ (millions)**	**% of total**
ALA-101 Manufacturing	2.4	19%
ALA-101 IND-enabling activities	0.7	6%
ALA-101 clinical trial activities	4.8	39%
Platform expansion (CLDN18.2 and IL-12-TM)	1.0	8%
IP	0.3	2%
Corporate	2.5	20%
Costs of the offer	0.8	6%
Total expected use of funds	**12.5**	**100%**

cGMP – Current Good Manufacturing Practice

Offer timetable

EVENT	DATE
Trading Halt	Friday 22 March
Placement bookbuild commenced	Friday 22 March
Firm Bids Due	2:00PM (AEDT) Monday 25 March
Acceptances Due	5:00PM (AEDT) Monday 25 March
ASX Announcement - Transaction, Investor Presentation, Trading Halt Lifted	Tuesday 26 March
Settlement of Placement Shares	Wednesday 3 April
Allotment of Placement Shares	Thursday 4 April

Key Risks

The Company considers that the following summary, which is not exhaustive, represents some of the major risk factors which investors ought to be aware of in evaluating the Company's business and risks:

Company and industry risks

The risks outlined below are specific to the Company's operations.

Dependency upon licence agreement

Access to the intellectual property rights to develop and commercialise CAR-iNKT cells in the field of oncology is predicated on the continuing operation of the license agreements in place between the Company and its licensors. Arovella is reliant on its licensors to have in place the relevant protection and rights to the technology as well as the authority to enter into the license agreements. Failure of a licensor or Arovella to comply with the terms of the licence agreements without an appropriate countermeasure could have a material adverse on Arovella's business, financial condition, operations or prospects.

Contractual risk

Any dispute or breakdown in the relationship between the Company and counterparties to its contracts including the licensors for its technologies, could adversely impact the business if the Company is in breach of any of its agreements and its counterparties seek to pursue the Company for breach of contract or enforce security interests against the Company's assets (and conversely the Company depends on such counterparties performing their obligations under such agreement).

Dispute with ZolpiMist licence and supply agreement counterparty

As previously advised by Arovella, the Company and the counterparty to a license and supply agreement for the ZolpiMist product, have been in commercial discussions regarding termination of the agreement. As part of these discussions, allegations of breach under the agreement have been made by each party against the other. The Company disputes any allegations made by the counterparty that it has breached the Agreement, and/or any entitlement of the counterparty to damages for breach alleged against Arovella. The agreement requires that any dispute between the parties be referred to arbitration. As at the date of this presentation, the parties are continuing commercial negotiations, and no arbitration has been commenced by either party. The outcome of the parties' commercial negotiations is, by its nature, uncertain, and there is a risk that the negotiations will not culminate in an agreed settlement, and/or that a settlement or potential arbitration proceedings may adversely impact the financial position of Arovella.

Product development and regulatory risk

Arovella's ability to commercialise its intellectual property is reliant on its ability to generate preclinical and clinical data, including in respect of the new therapies using CAR-iNKT cells, which the Company is developing. These new therapies must still undergo further clinical studies and those tests and trials may show that it does not work in a safe and effective manner. There can be no guarantee that relevant regulatory agencies will allow Arovella to undertake such trials and/or the development and approval process for any new products or applications of existing products may take longer, cost more than expected and may result in the Company not producing a viable product. Drug development is a highly risky business with a high rate of failure, including due to potential low therapeutic benefit and unacceptable toxicity. While the Company will conduct its clinical programs on the advice of consultants experienced in clinical trial design and regulatory affairs, there is no certainty that the trial design will provide appropriate data or that the data will meet the regulator's benchmark. This may require the Company to conduct further clinical studies, resulting in significant additional cost and delay. From the commencement of the clinical trial phase, the final drug development path typically takes between 7 to 11 years, depending on the indication.

Risk of delay and continuity of operations

Arovella may experience delay in achieving a number of critical milestones, including, completion of clinical trials, obtaining regulatory approvals, manufacturing, and securing commercial partners. Any material delays may impact adversely upon the Company, including the timing of results and the initiation and completion of clinical trials.

Key Risks (cont.)

Product manufacturing risk
Cell therapies, like Arovella's CAR-iNKT cell products, are complex therapeutics that relay on the use of a viral vector and human immune cells. The use of human immune cells as a raw material and the generation of a living therapeutic introduces the risk of variability between manufacturing runs. Arovella relies on the input of world-class consults, advisors and team members to manufacture its CAR-iNKT cell products and to prepare the documentation to support regulatory filings. Notwithstanding, there is no guarantee that Arovella will not require additional time and incur additional costs to define a manufacturing process, and collect the relevant documentation, that appeases regulators such as the FDA and support the use of the material in clinical trials and for commercialisation.

Intellectual Property
Arovella's ability to leverage its innovation and expertise depends on its ability to secure and protect its intellectual property and any improvements to it. The intellectual property may not be capable of being legally protected, it may be the subject of unauthorised disclosure or be unlawfully infringed, or the Company may incur substantial costs in asserting or defending its intellectual property rights. This includes Arovella's ability to obtain commercially valuable patent claims. Aside from the territories in which patents are currently granted, the patent applications are still pending, and additional patents are likely to be filed to provide for extensive protection.

Dependence upon key personnel
Arovella depends on the talent and experience of its personnel, and it may be difficult to replace them, or to do so in a timely manner or at comparable expense. The loss of services of one or more senior executives may have an adverse effect on the Company's operations.

Future capital requirements
Arovella is generally loss making and the Company will require substantial additional financing in the future to sufficiently fund its operations, research and development, manufacturing and clinical trials. Any additional equity financing may be dilutive to shareholders (who may not have the opportunity to participate in that raising), and may be undertaken at lower prices than any prior offer prices
Should the Company require additional funding, there can be no assurance that additional financing will be available on acceptable terms or at all. Any inability to obtain additional financing, if required, would have a material adverse effect on the Company's business, financial condition and results of operations. The Company's actual cash requirements may vary from those now planned and will depend upon many factors, including the continued progress of its research and development programs, the timing, costs and results of clinical trials, the cost, timing and outcome of submissions for regulatory approval and the status and timing of competitive developments.

Pipeline product in development and not approved for commercial sale
Arovella's ability to achieve profitability is dependent on several factors, including its ability to initiate and complete successful clinical trials, obtain regulatory approval its CAR-iNKT technology and successfully commercialise its products. There is not guarantee that Arovella's products will be commercially successful.

Regulatory and reimbursement approvals
The research , development, manufacture, marketing and sale of products using Arovella's technology are subject to varying degrees of regulation by a number of government authorities in Australia and overseas. Products developed using Arovella's technology must undergo a comprehensive and highly regulated development and review process before receiving approval for marketing. Products may also be submitted for reimbursement approval. The availability and timing of reimbursement approval may not be forthcoming and if it does, it may have an impact on the uptake and profitability of products in some territories.

Key Risks (cont.)

General Risks The future prospects of the Company's business may be affected by circumstances and external factors beyond the Company's control. Financial performance of the Company may be affected by a number of business risks that apply to companies generally and may include economic, financial, market or regulatory conditions. Some of these risks are outlined below.

Economic risks
The operating and financial performance of the Company is influenced by a variety of general economic and business conditions, including levels of consumer spending, inflation, interest rates, access to debt and capital markets, international economic conditions, significant acts of terrorism, hostilities or war or natural disasters, and government fiscal, monetary and regulatory policies. Prolonged deterioration in general economic conditions may have an adverse impact on the Company's business or financial condition. No guarantee can be made that the Company's market performance will not be adversely affected by any such market fluctuations or factors.

Market conditions
An investment in the Company's Shares has the general risks associated with any investment in the share market. Returns from an investment in Shares will depend on general stock market conditions as well as the performance of the Company. The market price of the Company's Shares can fall as well as rise and may be subject to varied and unpredictable influences on the market for equities in general. The trading price of the Company's Shares may be subject to fluctuations in response to factors such as actual or anticipated variations in the Company's operating results, announcements of new contracts by the Company or its competitors, announcements by the Company or its competitors of significant acquisitions, technological developments, capital commitments, additions or departures of key personnel and other events or factors, many of which are beyond the Company's control. Further, general share market conditions may affect the value of the Company's quoted securities regardless of the Company's operating performance. Share market conditions are affected by many factors such as: general economic outlook; interest rates and inflation rates; currency fluctuations; changes in investor sentiment; the demand for, and supply of, capital; and terrorism or other hostilities. Neither the Company nor the Directors warrant the future performance of the Company or any return on an investment in the Company.

Liquidity risk
The market for the Company's Shares may be illiquid. As a consequence, investors may be unable to readily exit or realise their investment.

Litigation risk
The Company is not currently engaged in any litigation. However, the Company is exposed to the risk of actual or threatened litigation or legal disputes in the form of customer claims, intellectual property claims, personal injury claims, employee claims and other litigation and disputes. If any claim was successfully pursued it may adversely impact the financial performance, financial position, industry standing, cash flow and share price of the Company.

Force majeure
Significant catastrophic events –such as war, acts of terrorism, pandemics, loss of power, cyber security breaches or global threats –or natural disasters -such as earthquakes, fire, or floods or the outbreak of epidemic disease –could disrupt the Company's operations, results and financial performance.

Taxation and government regulations
Changes in taxation and government legislation in a range of areas (for example, the Corporations Act, accounting standards, and taxation law) can have a significant influence on the outlook for companies and the returns to investors. The recoupment of taxation losses accrued by the Company from any future revenues is subject to the satisfaction of tests outlined in taxation legislation or regulations in the jurisdictions in which the Company operates. There is no guarantee that the Company will satisfy all of these requirements at the time it seeks to recoup its tax losses which may impact on the financial performance and cash flows of the Company.

Key Risks (cont.)

Insurance risk
The Company intends to insure its operations in accordance with industry practice. However, in certain circumstances, the Company's insurance may not be of a nature or level to provide adequate insurance cover. The occurrence of an event that is not covered or fully covered by insurance could have a material adverse effect on the business, financial condition and results of the Company.

Nature of investment
There are inherent risks associated with investment in any Company. Shares in the Company do not guarantee payment of dividends, return on capital or maintenance of capital or value. No assurances can be given that shares will be valued at or above the purchase price or that they may be sold at any price. The value of the shares may vary depending on the financial and operating performance of the Company and external factors over which the Company and its directors have no control, including changes to the market.

Concluding comment
The above list of risk factors ought not to be taken as an exhaustive one of the risks faced by Arovella or by investors in the Company. The above factors, and others not specifically referred to above, may in the future materially affect the financial performance of Arovella and the value of its Shares. Therefore, the Shares to be issued carry no guarantee with respect to the payment of dividends, returns of capital or the market value or price at which those Shares may be traded.
Investment in Arovella must be regarded as highly speculative and neither Arovella nor any of its Directors or any other party associated with the preparation of this presentation guarantee that any specific objectives of Arovella will be achieved or that any particular performance of Arovella or of the Shares, will be achieved.

ASX:**ALA**

arovella THERAPEUTICS

Thank You

Dr. Michael Baker

CEO & Managing Director

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Mobile: +61 403 468 187

Cell therapy deal references

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12. *https://www.nasdaq.com/articles/athenex-snaps-up-kuur-therapeutics-for-$185m-street-sees-133.7-upside-2021-05-05*
13. *https://eternatx.com/news/brooklyn-immunotherapeutics-completes-acquisition-of-eterna-therapeutics/*