

ASX: ALA

Arovella Therapeutics Limited
ACN 090 987 250



ASX Release

21 November 2023

MONSOON TWILIGHT INVESTOR BRIEFING PRESENTATION

Highlights:

- **Arovella to present at the Monsoon Twilight Investor Briefing**

MELBOURNE, AUSTRALIA 21 November 2023: Arovella Therapeutics Ltd (ASX: ALA), a biotechnology company focused on developing its invariant Natural Killer T (iNK) cell therapy platform, is pleased to announce that its CEO and MD, Dr Michael Baker, will today present at the Monsoon Twilight Investor Briefing in Melbourne.

Dr Baker will present key pre-clinical data for Arovella's iNKT cell therapy platform and described how Arovella's technology provides important advantages over existing T-cell therapies and has the potential to be applied to both blood cancers and solid tumours. The presentation is attached to this release and is also available on the Company's website <https://www.arovella.com/investor-presentations>.

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

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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 is also expanding into solid tumour treatment through its CLDN18.2-targeting technology licensed from Sparx Group. Additional tumour targeting technologies are anticipated to be used in conjunction with Arovella's iNKT cell therapy platform. 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 α -GalCer 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.

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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.

The Company is also commercialising ZolpiMist™ to treat short-term insomnia.

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.

ASX:ALA



monsoon

communications

Monsoon Twilight Briefing

November

2023



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Arovella's strengths

Off-the-Shelf iNKT Cell Platform

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

Lead Product Advancing to Clinic

ALA-101, a potential treatment for CD19-expressing blood cancers, progressing 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 our cell therapy platform and align with our focus areas

Unique Value Proposition

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





About Cell Therapy

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 2030¹

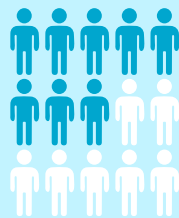


Cure

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



Strong Sales



40-60%

Patients relapse post-CAR-T therapy²

Product	Approval Year	2022 Revenue
 YESCARTA <small>(axicabtagene ciloleucel)</small>	2017	US\$1160m ³
 KYMRIAH <small>(tisagenlecleucel)</small>	2017	US\$536m ⁴
 Abecma <small>(idecabtagene vicleucel)</small>	2021	US\$388m ⁵

- <https://www.businesswire.com/news/home/20230529005130/en/Global-Cell-in-Therapy-Market-Report-2023-Advancements-in-Biotechnology-Drives-Growth---ResearchAndMarkets.com>
- Zinzi et al., 2023 *Pharmacological Research* - 10.1016/j.phrs.2023.106742
- https://s29.q4cdn.com/585078350/files/doc_financials/2022/q4/GILD-Q4-FY22-Earnings-Press-Release-2-February-2023.pdf
- https://www.novartis.com/sites/novartis_com/files/q4-2022-media-release-en.pdf
- <https://bioprocessintl.com/bioprocess-insider/therapeutic-class/bms-sees-car-t-sales-rocket-in-line-with-increased-capacity/#:~:text=For%20the%20full%20year%202022,%2487%20million%20the%20year%20prior>

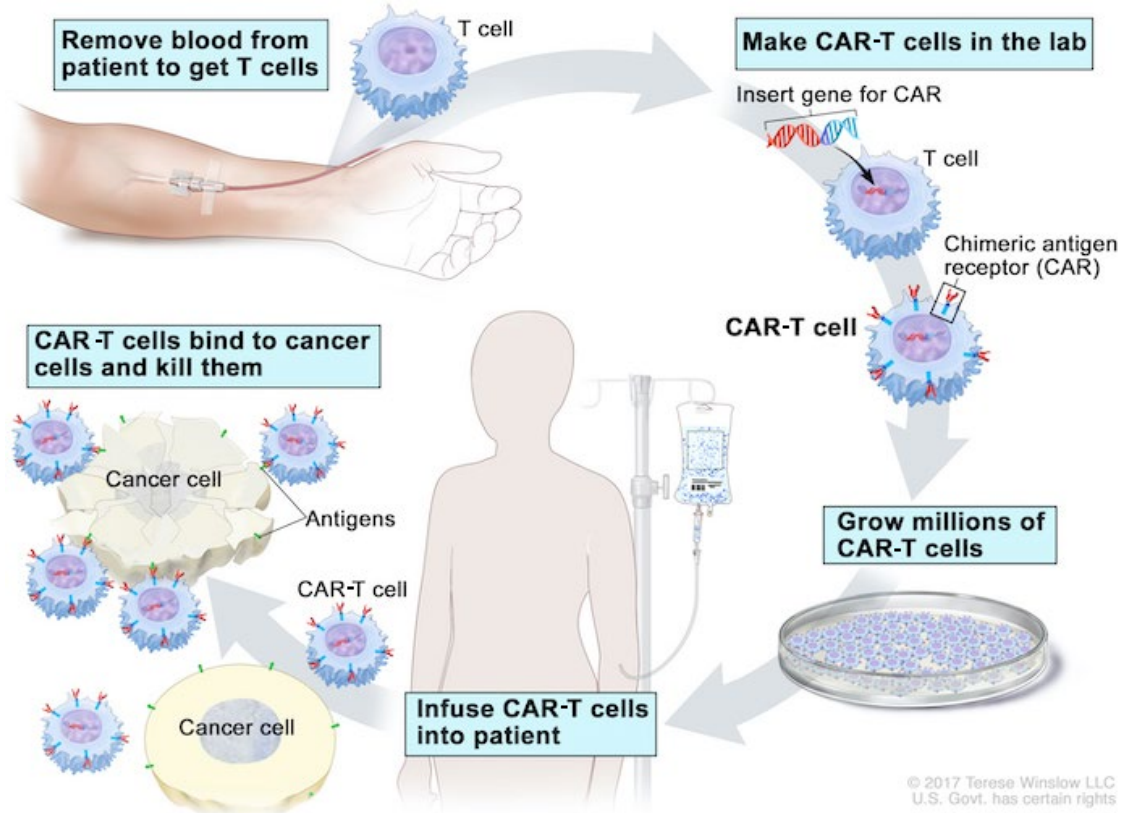


Emily Whitehead - Celebrating 10 years of CAR-T cell therapy

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

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.

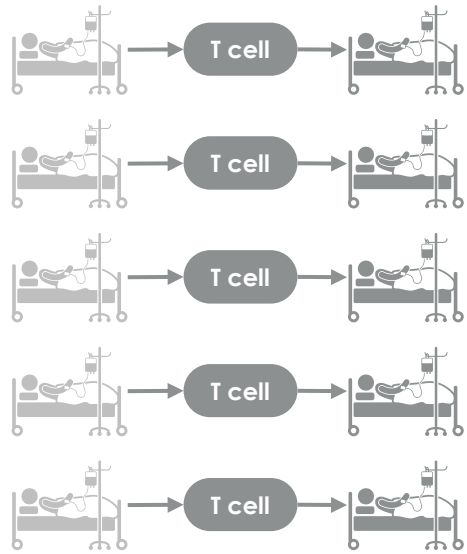


CAR-T cells find & kill tumour cells

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.

CAR-T cell therapies pose challenges

The current supply chain results in very high costs



T cells must originate from the patient

Each manufacturing batch is patient-specific

Manufacturing & supply chain costs are high



High drug pricing (>US\$500k per patient)

T cells can be compromised due to disease



Potential reduction in efficacy

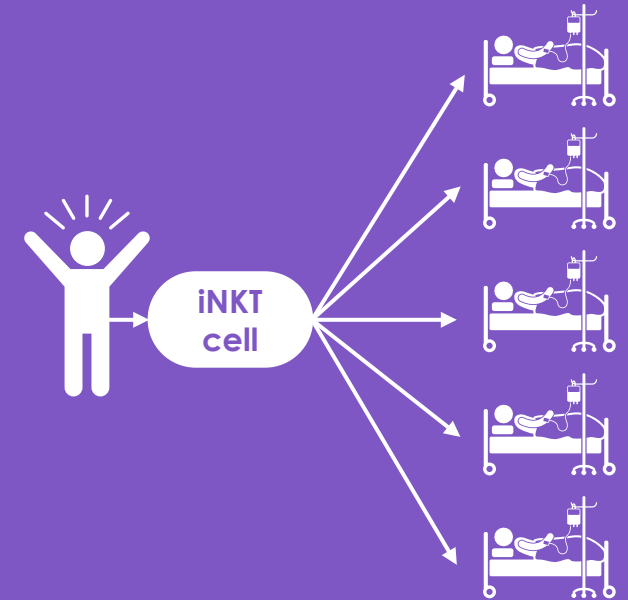
Limited centres can collect and manufacture



Limits patient access

Arovella's **off-the-shelf CAR-iNKT** cell platform

with potential for improved efficacy

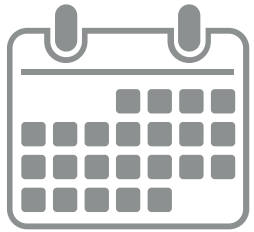


Allogeneic

A single healthy donor batch = treatment for multiple patients

CAR-T cell therapies pose challenges

The manufacturing time can block patient access



4-6 weeks
manufacturing
time

Patient must wait for
therapy to be
manufactured

**Patient may
die waiting for
treatment**



Time is an issue
for patients with
aggressive disease

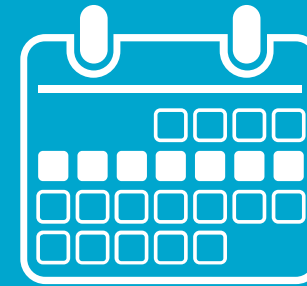
**Manufacturing
run failures
can occur**



Further increasing
the time to treatment
(and cost)

Arovella's **off-the-shelf
CAR-iNKT** cell platform

with potential for improved efficacy



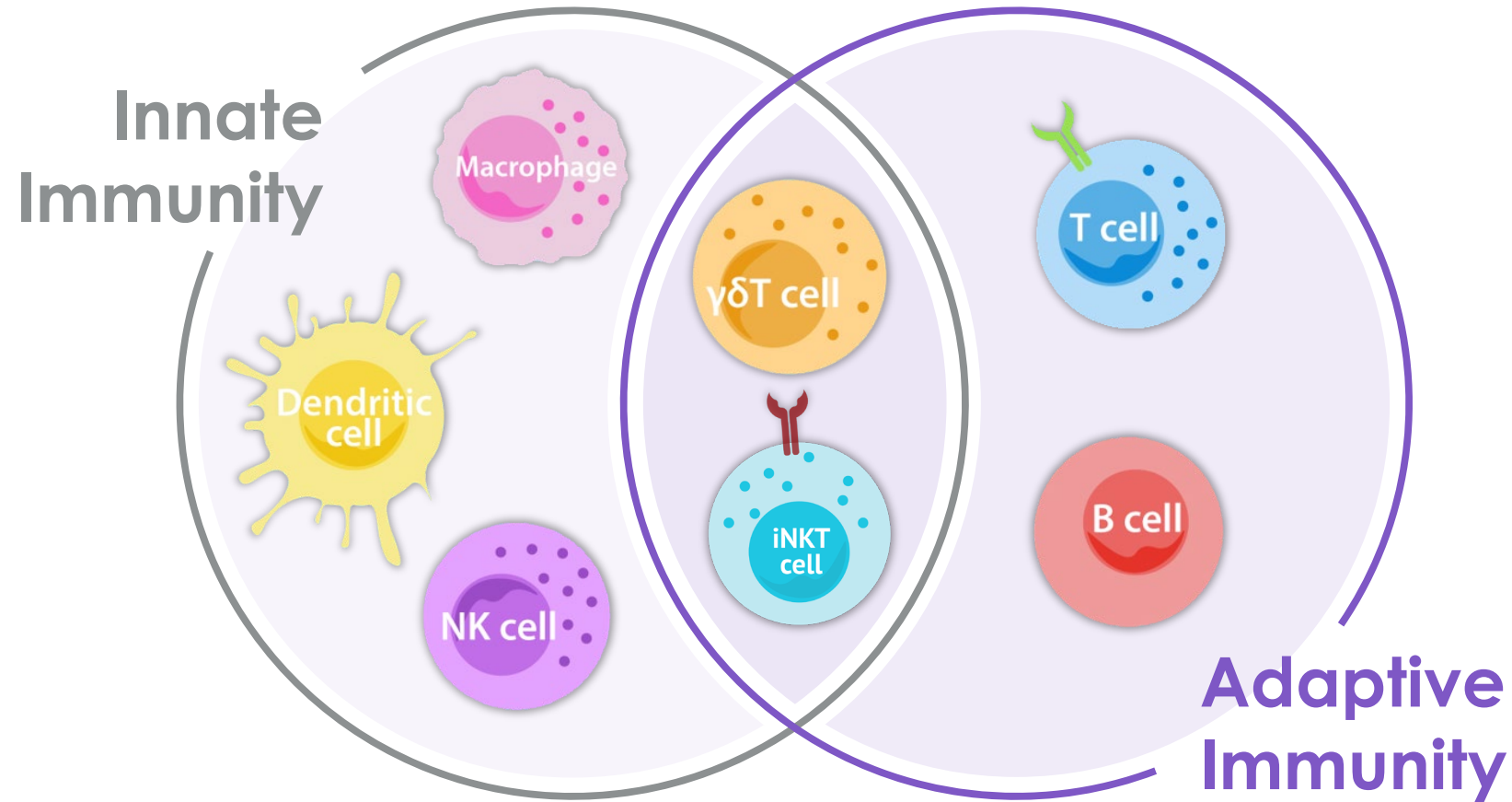
1 week



Patients ready to dose
within 1 week

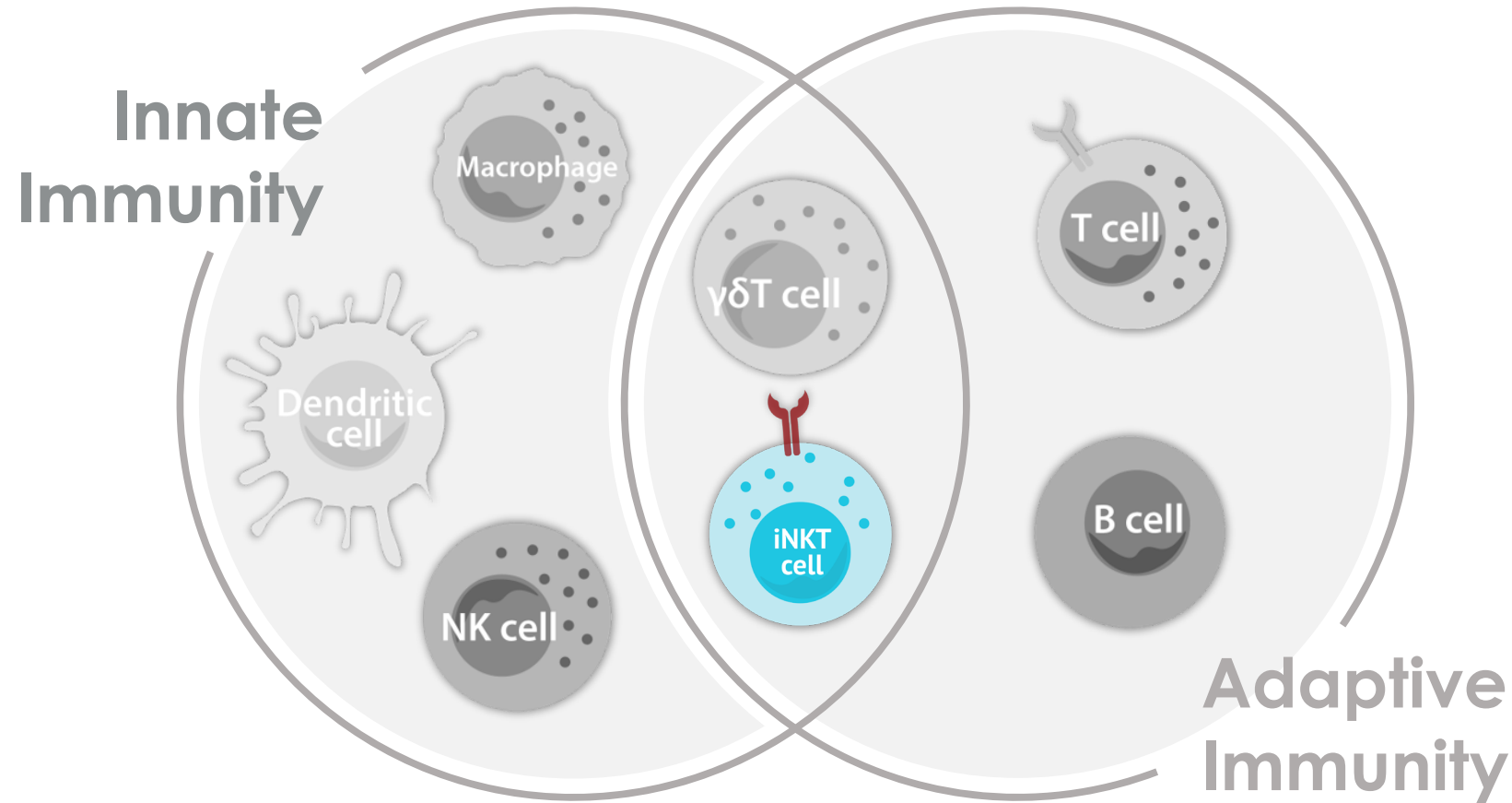
Introducing invariant Natural Killer T (iNKT) cells

Bridging the innate and adaptive immune system



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

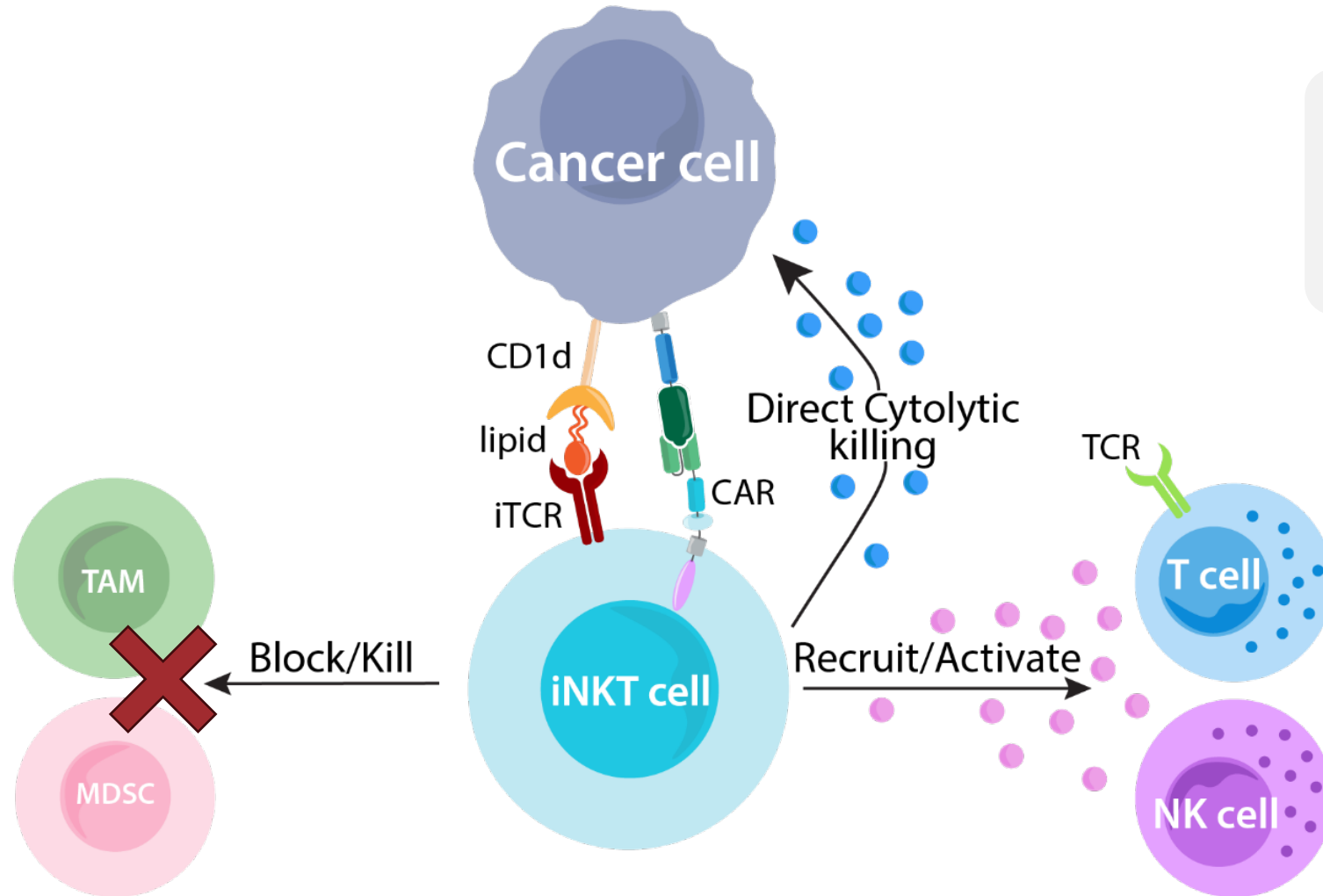
- Bridge innate & adaptive immune responses
- Contain both T cell & NK cell killing mechanisms
- Naturally target & kill cancers that express CD1d

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

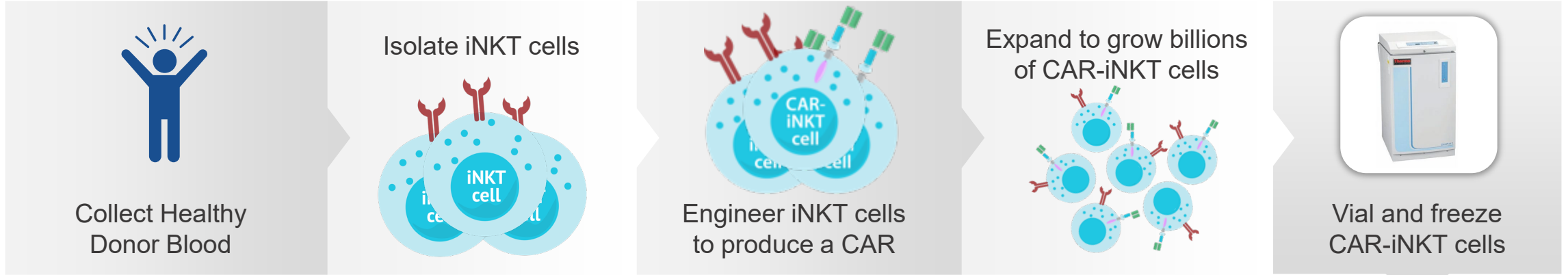


TAM	Tumour Associated Macrophage
MDSC	Myeloid Derived Suppressor Cell
CAR	Chimeric Antigen Receptor
NK	Natural Killer

CAR-iNKT cell therapy production advantages

Off-the-shelf manufacturing advantages

MANUFACTURING



Healthier starting material

Potentially better efficacy



Scalable manufacturing with reduced costs

Reach more patients



Faster access to treatment

Improved outcomes for aggressive cancers

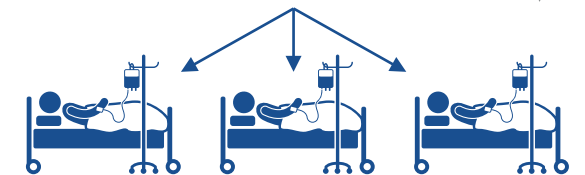


Removes risk of manufacturing run failure

Thaw CAR-iNKT cells



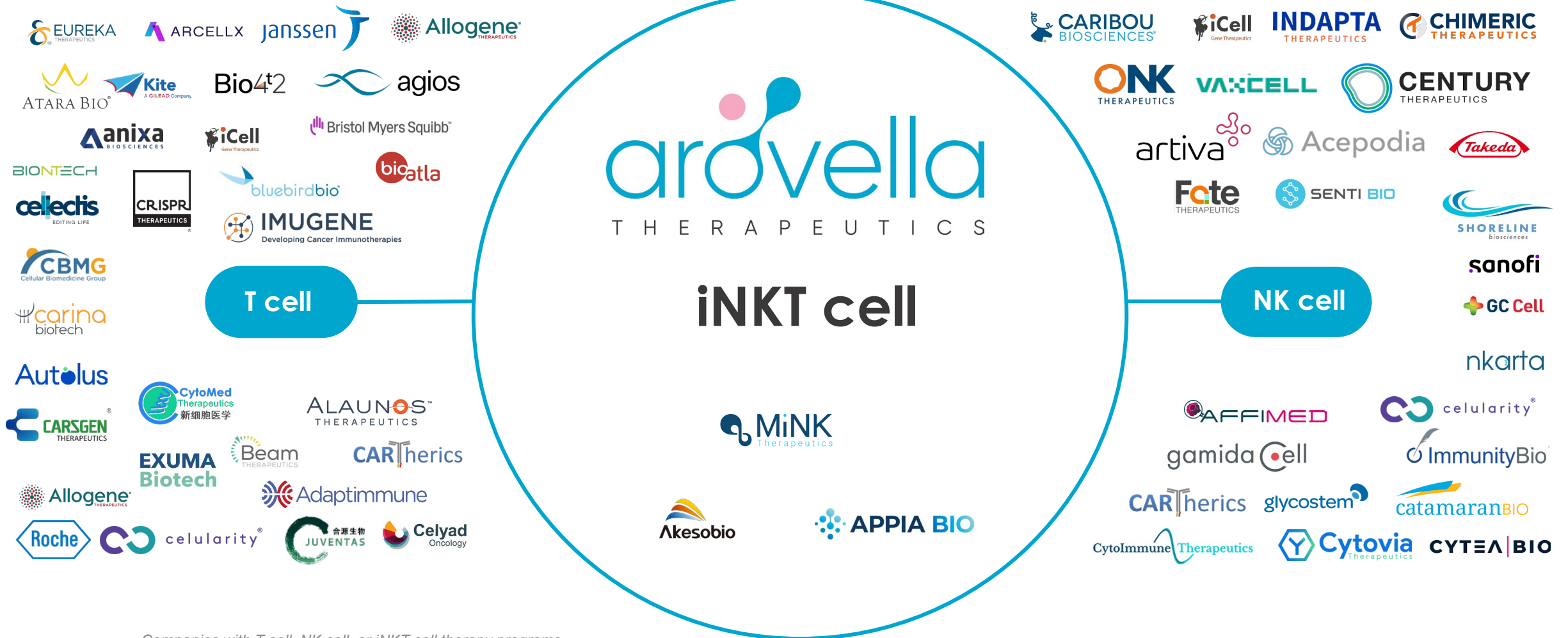
Dose eligible patients



TREATMENT

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

About ALA-101 (CAR19-iNKT cells)

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



CD19+ hematological malignancies

Targeting CD19+ blood cancers

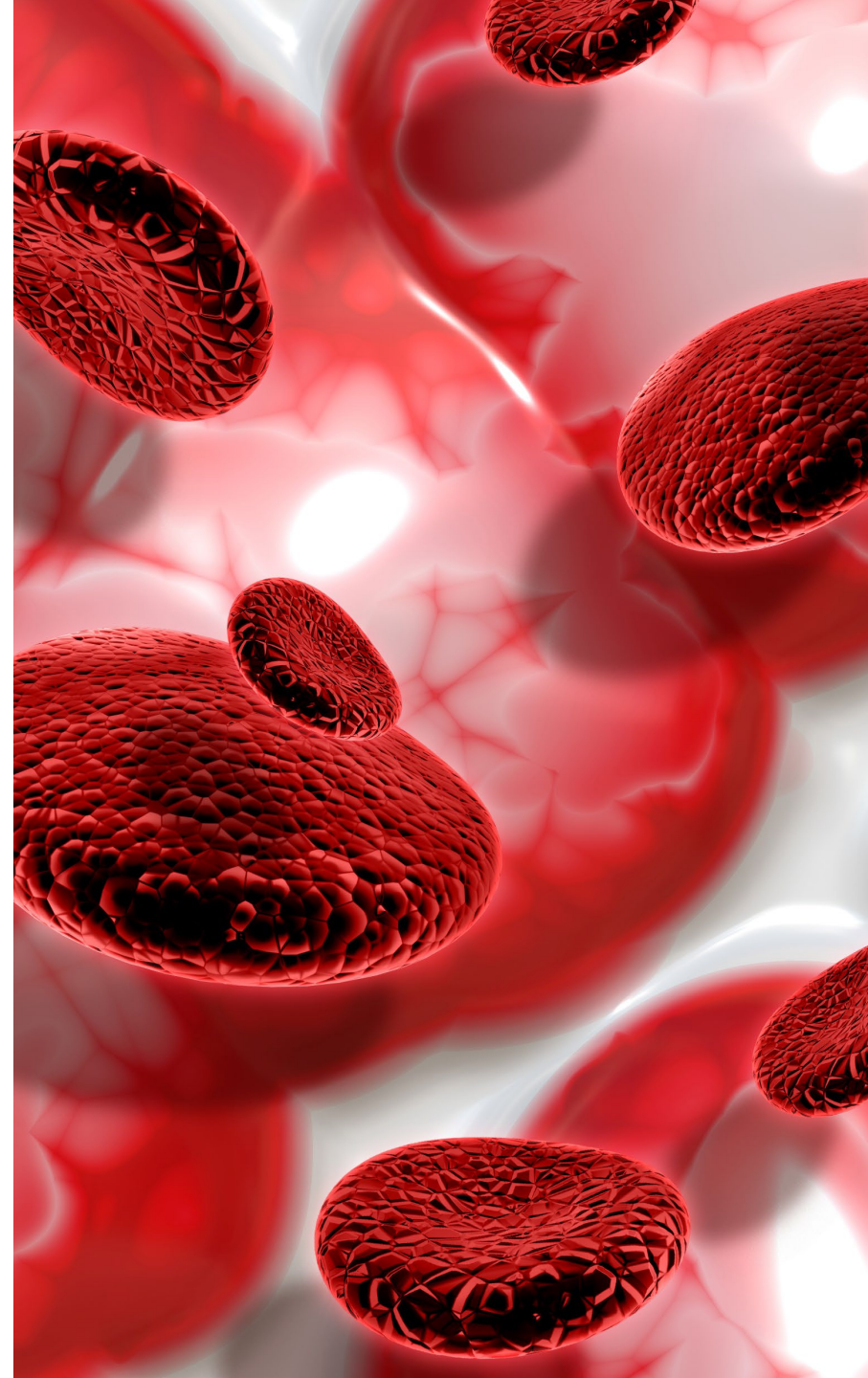
**CD19+
lymphomas
and CD19+
leukemias**

>140k cases in the US in 2023^{1,2}

>40k deaths^{1,2} in the US in 2023

CAR-T products are moving to second line therapy

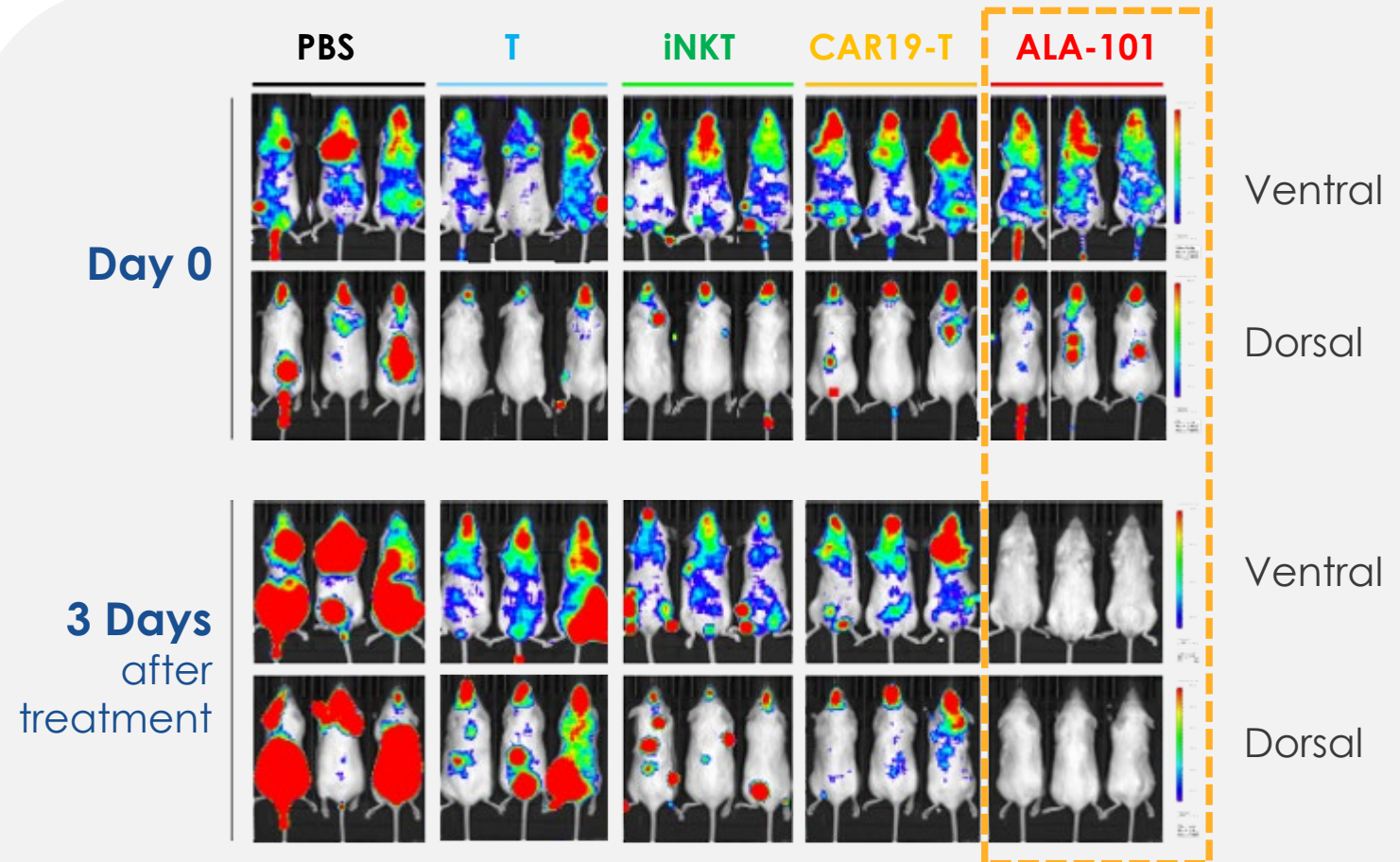
No allogeneic cell therapy approved to date for blood cancers



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
- After three days, ALA-101 resulted in significant regression of tumour cells
- In all other treatments, we observed strong tumour cell persistence
- ALA-101 displays swift action

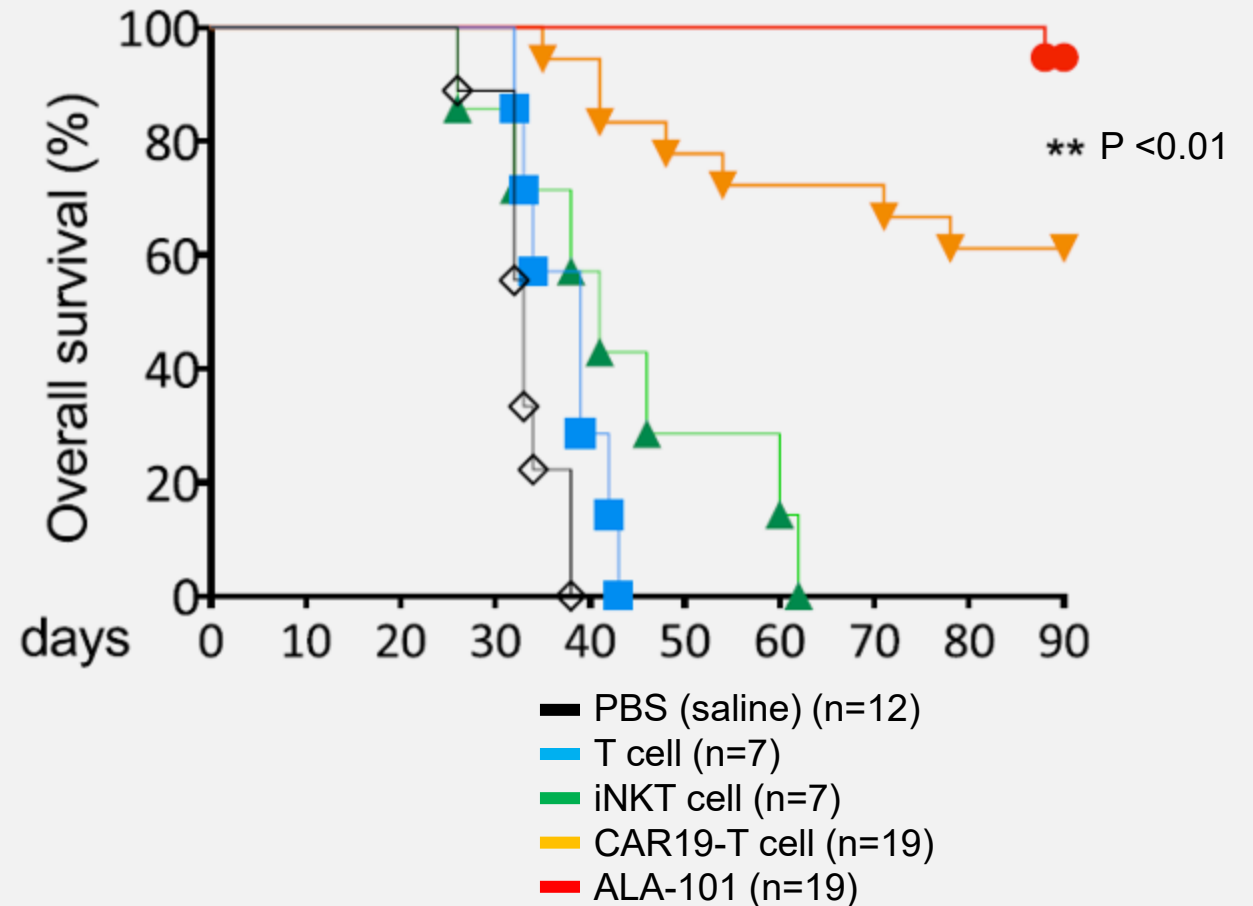


Rotolo *et al.*, Cancer Cell (2018)

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
- 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

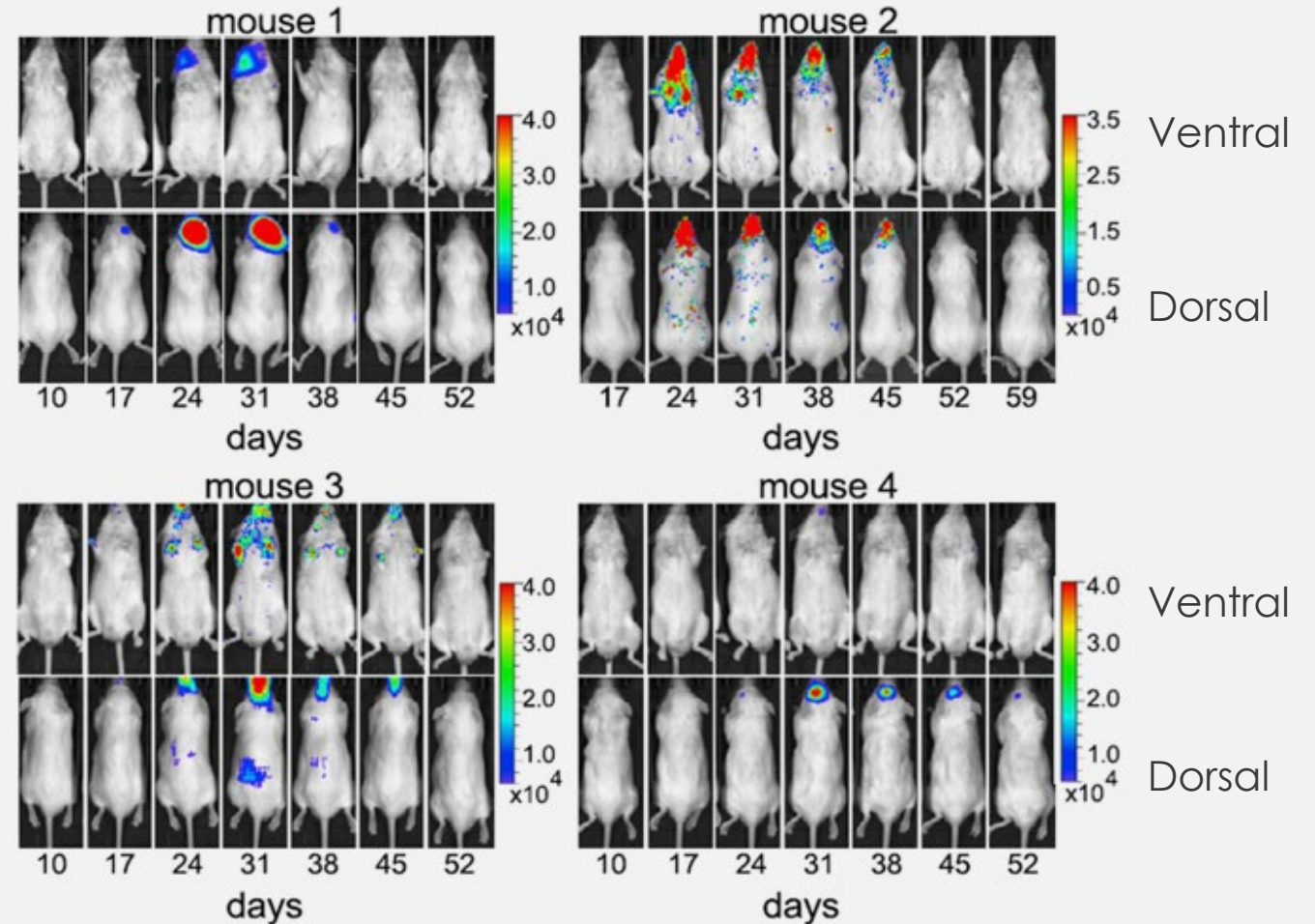


Rotolo et al., Cancer Cell (2018)

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 generated with clinical-design lentiviral vector in animal models using thawed, “off-the-shelf” ALA-101.



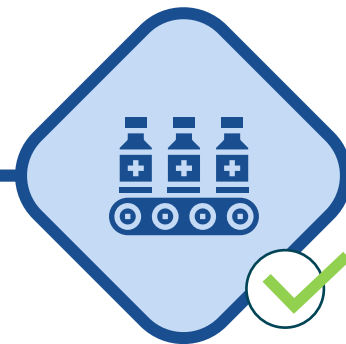
Expected to be Safe

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.

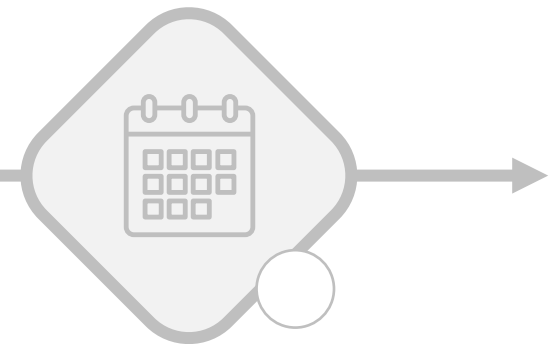
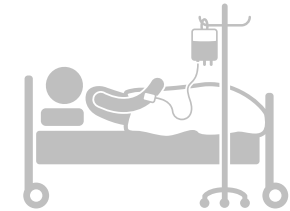


Multiple Dose Manufacturing

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



Phase 1 Clinical Trial



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



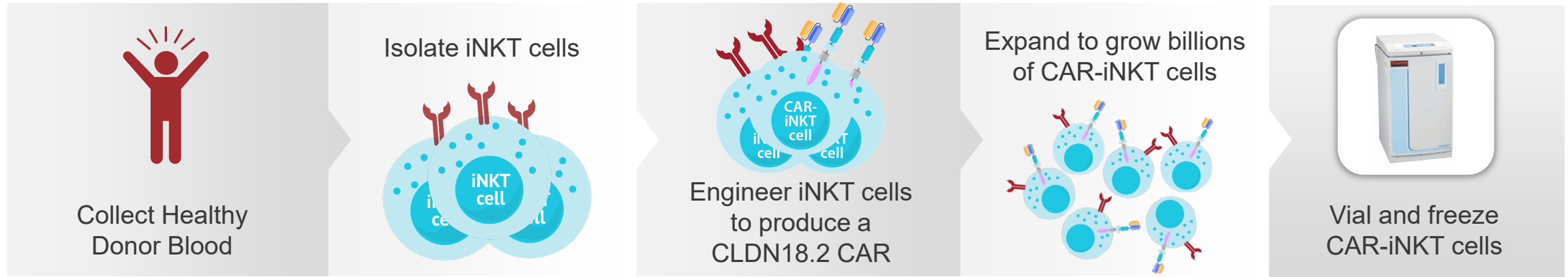
Create unique partnerships

Create partnerships to use novel combination therapies with synergistic effects

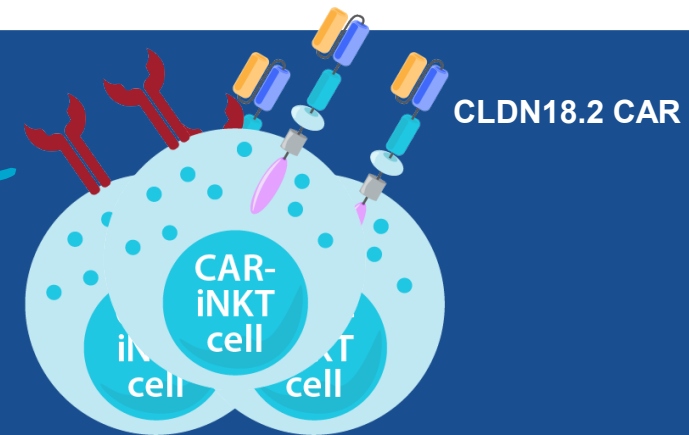
Manufacturing CLDN18.2-iNKT cells

Generation of CLDN18.2-iNKT cells will leverage existing manufacturing process

MANUFACTURING



Arovella will use its **proprietary manufacturing process** to create CLDN18.2-iNKT cells



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)

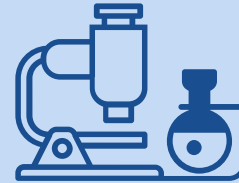
gastroesophageal junction cancer (GEJC)

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

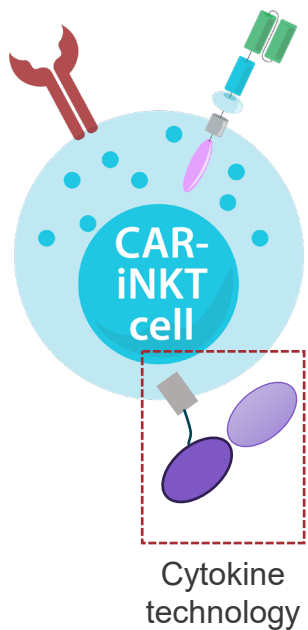
market alone expected to reach **\$10.7 billion** by 2031¹

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

“Armouring” iNKT cells

Cytokine technology enhances activity of iNKT cells in solid tumours

Cytokine technology



Adding specialised cytokines to iNKT cells can **increase persistence of the cells** (*how long they last in the body*) and increase anti-tumour activity

Exclusive option

with University of North Carolina for cytokine technology developed by Prof. Gianpietro Dotti

Cytokine technology is incorporated into the lentiviral vector and

does not require changes to the manufacturing process

iNKT cells + cytokine technology

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

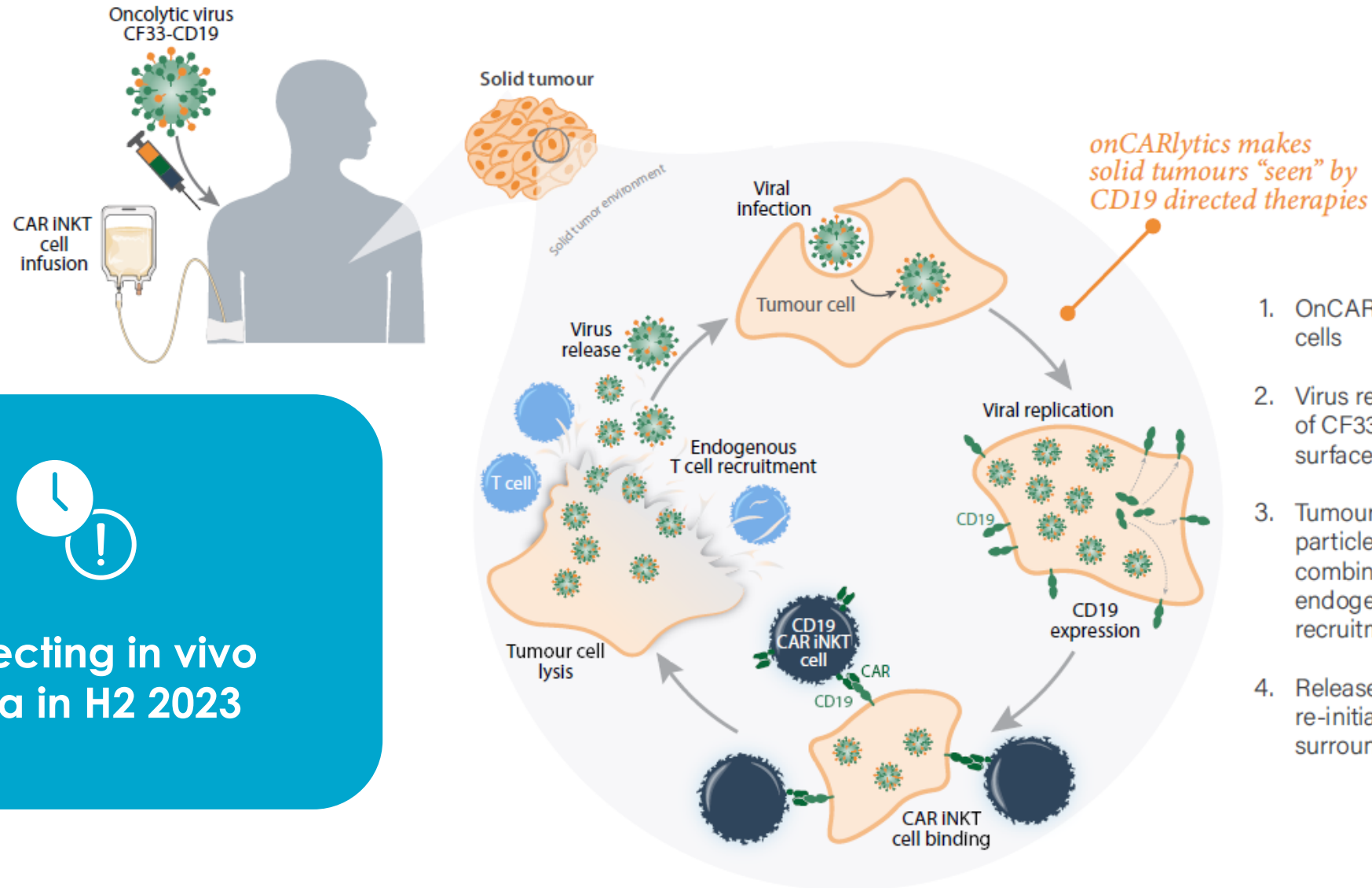
75%+ of mice treated with CAR-iNKT cells *containing the cytokine* were **alive at 61 days**

VS

0% of mice treated with CAR-iNKT cells *lacking the cytokine* were **alive at 49 days**

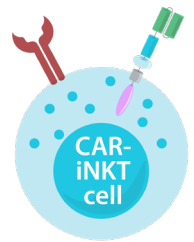
ALA-101 & Imugene's onCARlytics

Imugene's onCARlytics platform may make solid tumours sensitive to ALA-101



Expecting in vivo data in H2 2023

Arovella's expanding pipeline



CD19-CAR



CD19-CAR



Oncolytic virus
CF33-CD19



Novel Targets

Introduction of CLDN18.2

ALA-101

ALA-101 + onCARlytics

CLDN18.2

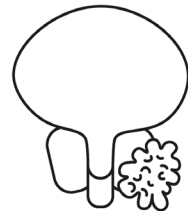
Cytokine Technology



Non-Hodgkin's
Lymphoma



Head and
Neck Cancer



Prostate
Cancer



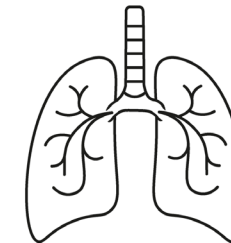
Brain
Metastases



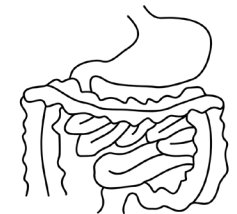
Triple negative
breast cancer



Pancreatic
Cancer



Lung Cancer



Gastric
Cancers

Milestones for FY2024



June
2023



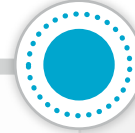
ALA-101

- Complete process optimisation and scale-up in preparation for cGMP manufacture
- Complete production of cGMP lentiviral vector
- Finalise clinical trial plan for Phase 1 study

iNKT Cell
Therapy
Platform

- Confirm the activity of ALA-101 cells when combined with Imugene's onCARlytics to target solid tumours in animal models
- In-licence cytokine technology currently under option (pending due diligence)

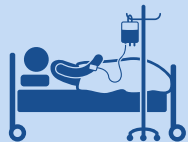
December
2023



- Complete cGMP manufacture for Phase 1 clinical trials
- Complete preparatory activities for Phase 1 study, including submission of regulatory dossier, engagement with clinical sites and KOLs

- Initiate proof-of-concept testing for CLDN18.2-iNKT cells to expand iNKT platform for treatment of solid tumours

June
2024



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



Continue to enhance the platform and expand the pipeline

Expand the use of the iNKT platform to treat solid tumours

Financial overview

Financial Snapshot

ASX CODE	ALA
Market capitalisation ¹	\$81.5 million
Shares on issue	906.31 million
52-week low / high ¹	\$0.020 / \$0.105
Cash Balance (September 30 2023)	\$5.32 million
R&D tax rebate received 20 November 2023	\$1.95 million

Major Shareholders



























Shareholder	Ownership (%) ¹
THE TRUST COMPANY (AUSTRALIA) LIMITED	59,397,161 (6.66%)
RICHARD JOHN MANN	50,905,657 (5.71%)
UBS NOMINEES PTY LTD	20,620,196 (2.31%)
BLACKBURNE CAPITAL PTY LTD	18,325,000 (2.05%)
DYLIDE PTY LTD	15,666,666 (1.76%)

1. As of 8 November 2023

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)
Nov-23	Collaboration and investment	 AstraZeneca	 cellectis	Not specified	Platform	\$25	\$70-220 per product	
Aug-23	Licence ²	 IMUGENE Developing Cancer Immunotherapies	 PRECISION BIOSCIENCES	T Cell	Phase 1b	\$21	\$206	\$227
Aug-23	Strategic investment (ROFR) ³	 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 ⁴	 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
Dec-19	Acquisition	 astellas	 XYPHOS	Multiple	Preclinical	\$120	\$545	\$665

1. See Slide 33 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

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-expressing blood cancers, is being progressed to Phase 1 clinical trials, expected to commence in 2024

Improved manufacturing logistics

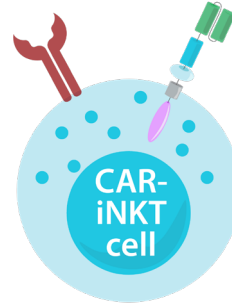
Allogeneic CAR-iNKT cells will significantly improve logistics and increase patient access



Arovella has an expanding pipeline

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

Arovella's CAR-iNKT Cell Platform



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

ASX:ALA



Thank You

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