

ASX: ALA

Arovella Therapeutics Limited
ACN 090 987 250



ASX Release

5 February 2026

EUROZ HARTLEYS 2026 HEALTHCARE FORUM PRESENTATION

Highlights:

- **Arovella presents at the Euroz Hartleys 2026 Healthcare Forum**
- **Arovella conducting non-deal roadshow in Perth, Sydney and Melbourne**

MELBOURNE, AUSTRALIA 5 February 2026: Arovella Therapeutics Ltd (ASX: ALA), a biotechnology company focused on developing its invariant Natural Killer T (iNKT) cell therapy platform, is pleased to provide an update to investors in the form of the attached presentations.

Arovella's CEO and Managing Director, Dr Michael Baker, will be presenting at the Euroz Hartleys 2026 Healthcare Forum in Perth today.

In addition, Dr Baker will be holding non-deal investor meetings in Perth, Sydney and Melbourne from 5th-10th of February.

Both presentations are attached to this announcement and can be viewed on the Company's website www.arovella.com.au.

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

Dr Michael Baker

Chief Executive Officer & Managing Director

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NOTES TO EDITORS:**About Arovella Therapeutics Ltd**

Arovella Therapeutics Ltd (ASX: ALA) is a biotechnology company focused on developing its invariant natural killer T (iNKT) cell therapy platform from Imperial College London to treat blood cancers and solid tumours. Arovella's lead product is ALA-101. ALA-101 consists of CAR19-iNKT cells that have been modified to produce a Chimeric Antigen Receptor (CAR) that targets CD19. CD19 is an antigen found on the surface of numerous cancer types. iNKT cells also contain an invariant T cell receptor (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.

ASX:ALA



arovella
T H E R A P E U T I C S

Investor Presentation

Euroz Hartleys 2026 Healthcare Forum

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Arovella's Investment Highlights

A high-angle photograph of a swimmer in a pool, viewed from above. The swimmer is in the middle of a stroke, with their arms extended forward and their head above water. The pool is blue, and there are lane lines visible. The swimmer is wearing a black cap and dark swim trunks. The water is slightly rippled around the swimmer.

U.S. FDA IND Accepted for ALA-101¹

U.S. FDA IND secured for ALA-101, and anticipate commencing phase 1 clinical trials in FY 2026 for CD19-positive blood cancers

Addressing Key Unmet Need

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

Strategic Acquisitions

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

Off-the-Shelf iNKT Cell Platform

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

Clinic-ready Manufacturing Process

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

Strong Leadership Group

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

¹. Date is indicative only, based on current estimates and subject to change.

IND accepted by U.S. Food and Drug Administration (FDA)

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

Key operational and regulatory milestone



Provides regulatory validation of ALA-101's preclinical package, manufacturing process, and clinical development plan



Enables Arovella to conduct its phase 1 trial in Australia and the U.S. for patients with CD19-positive lymphoma and leukaemia



Ended December quarter at \$19.4 million, enough to reach preliminary clinical safety and efficacy readouts for ALA-101



Provides the framework for future IND applications targeting solid tumours, including ALA-105, and new CARs

Arovella's path to patient



PRODUCT	TECHNOLOGY ACQUISITION	PRE-CLINICAL CONFIRMATION	LENTIVIRUS MANUFACTURING	MANUFACTURING PLATFORM	FDA IND	PHASE 1 CLINICAL TRIAL ¹	PHASE 2 CLINICAL TRIAL
CD19 CAR-iNKT Lymphoma ALA-101 	✓	✓	✓	✓	✓	FY 2026	
CLDN18.2 CAR-iNKT Gastric cancer and pancreatic cancer ALA-105 	✓			✓			
CAR-iNKT Other cancers (i.e. GD2, GPC3) 				✓			


 The IND for **ALA-101** has been **accepted by the FDA** to commence first-in-human clinical trials


 Arovella's CLDN18.2 CAR demonstrates **robust killing** of pancreatic cancer cell lines expressing CLDN18.2


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

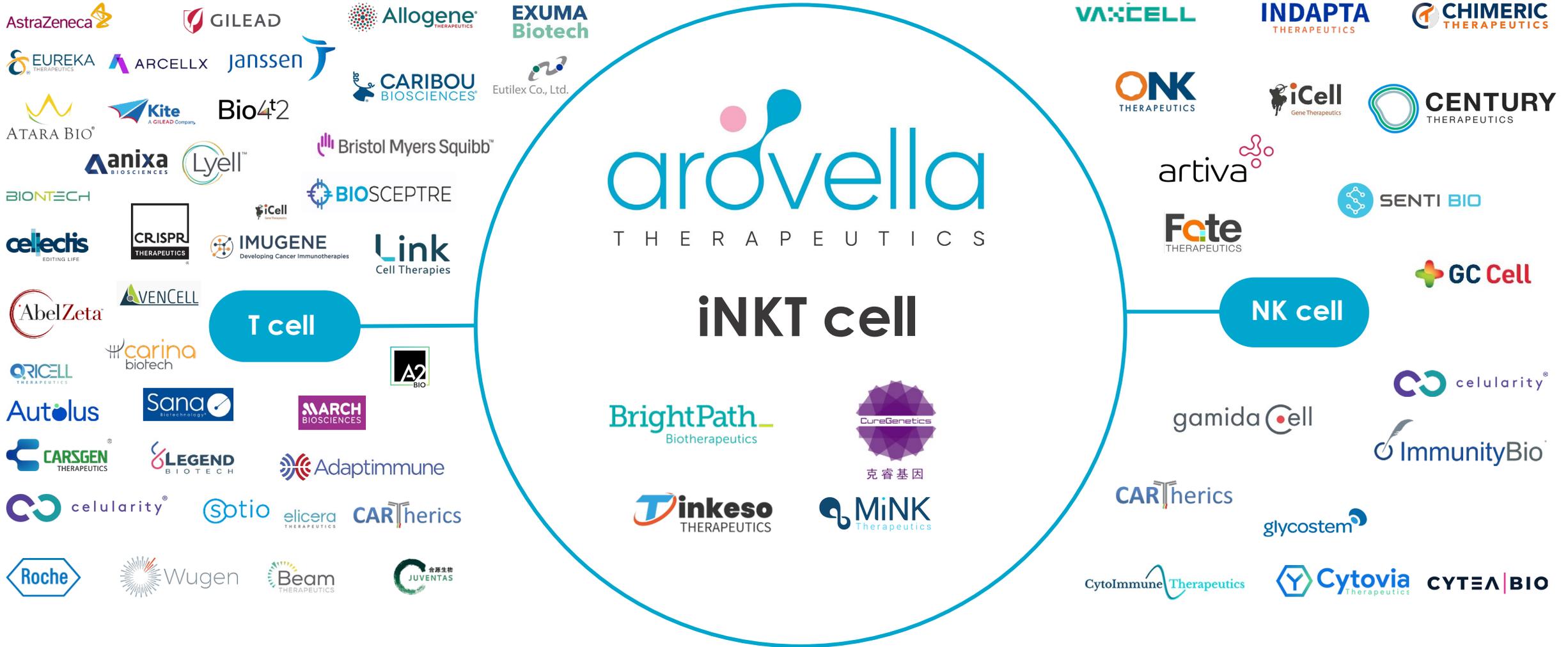
Recent cell therapy transactions¹

Date	Type of deal	Acquirer/Licensee	Target/Licensor	Cell Type	Stage	Upfront (US\$M)	Milestones (US\$M)	Total deal value (US\$M)
Oct-25	Acquisition	 Bristol Myers Squibb	 ORBITAL THERAPEUTICS	In vivo CAR	Preclinical ²	\$1,500	\$0	\$1,500
Aug-25	Acquisition	 Kite A GILEAD Company	 interius	In vivo CAR	Phase 1	\$350	\$0	\$350
Jun-25	Acquisition	 abbvie	 capstanx™	In vivo CAR	Phase 1	\$2,100	\$0	Up to \$2,100
Mar-25	Acquisition	 AstraZeneca	 EsoBiotec	In vivo CAR	Phase 1	\$425	\$575	\$1,000
Nov-24	Acquisition	 Roche	 POSEIDA THERAPEUTICS	Allo T cell	Phase 1	~\$1,038	~\$462	\$1,500
Dec-23	Acquisition	 AstraZeneca	 GRACELL	T Cell	Phase 1b	\$1,000	\$200	\$1,200
Aug-23	Licence 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	
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	 Kite A GILEAD Company	 APPIA BIO	iNKT Cell	Preclinical	undisclosed	undisclosed	\$875
May-21	Acquisition	 Athenex	 kuur THERAPEUTICS	iNKT Cell	Phase 1	\$70	\$115	\$185

1. See the last slide for deal references; 2. Preclinical data in non-human primates - <https://www.orbitaltx.com/orbital-therapeutics-presents-non-human-primate-data-for-in-vivo-car-t-therapy-with-potential-best-in-class-profile-for-autoimmune-disease>; 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

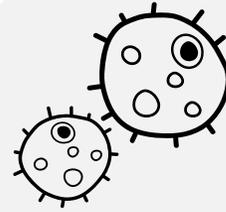
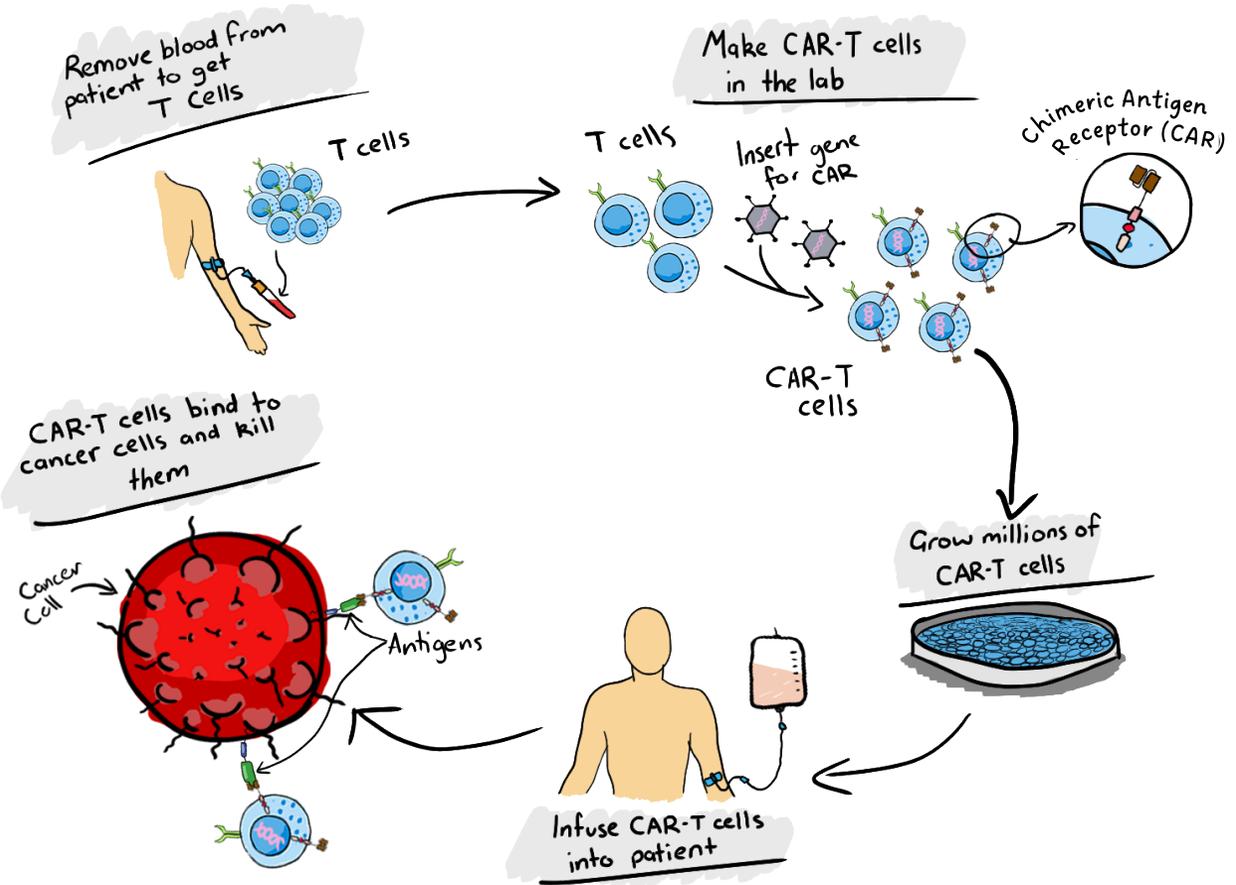




About CAR-T cells

How original CAR-T cell therapies work

CAR-T cell therapy is personalised medicine



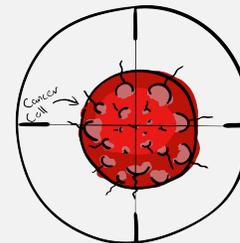
T cells = immune cell

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.

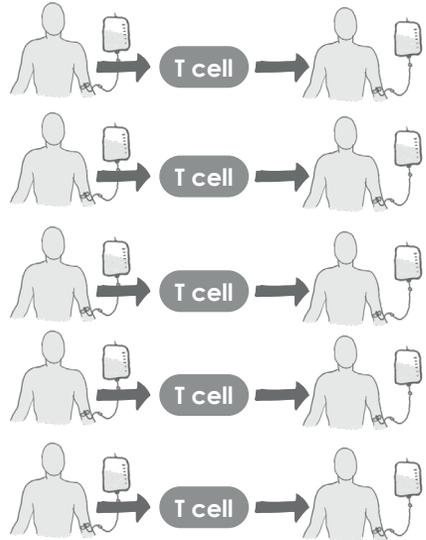


CAR-T cells find & kill tumour cells

CAR-T cells are administered to the patient to find and kill the cancer cells. Once the CAR recognizes and binds to the target antigen on the cancer cell, the CAR-T cell is activated to kill the cancer cell.

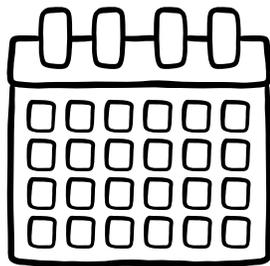
Current CAR-T technology challenges

One CAR-T product **only** treats the patient who supplied the T cells



Each manufacturing batch is **patient-specific**

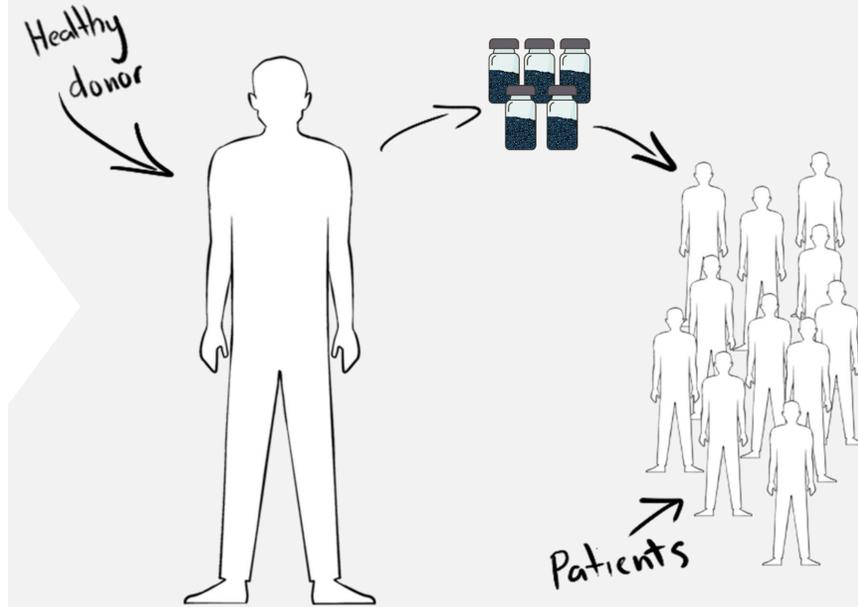
Patient must wait **3-4 weeks** for therapy



-  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

ALA's solution:

One CAR-iNKT batch from **a healthy donor** treats multiple patients



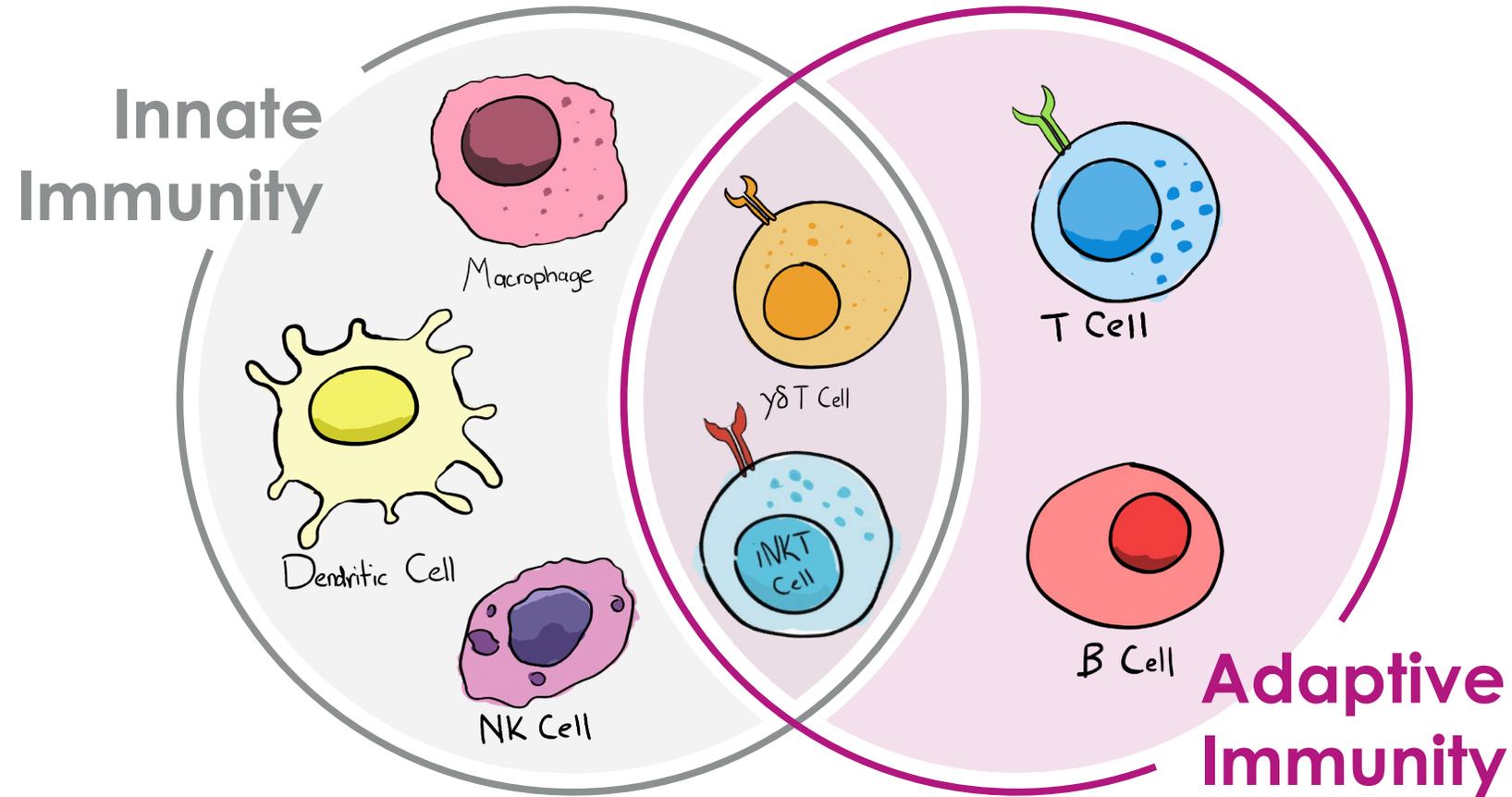
1 week

Patients ready to dose within 1 week



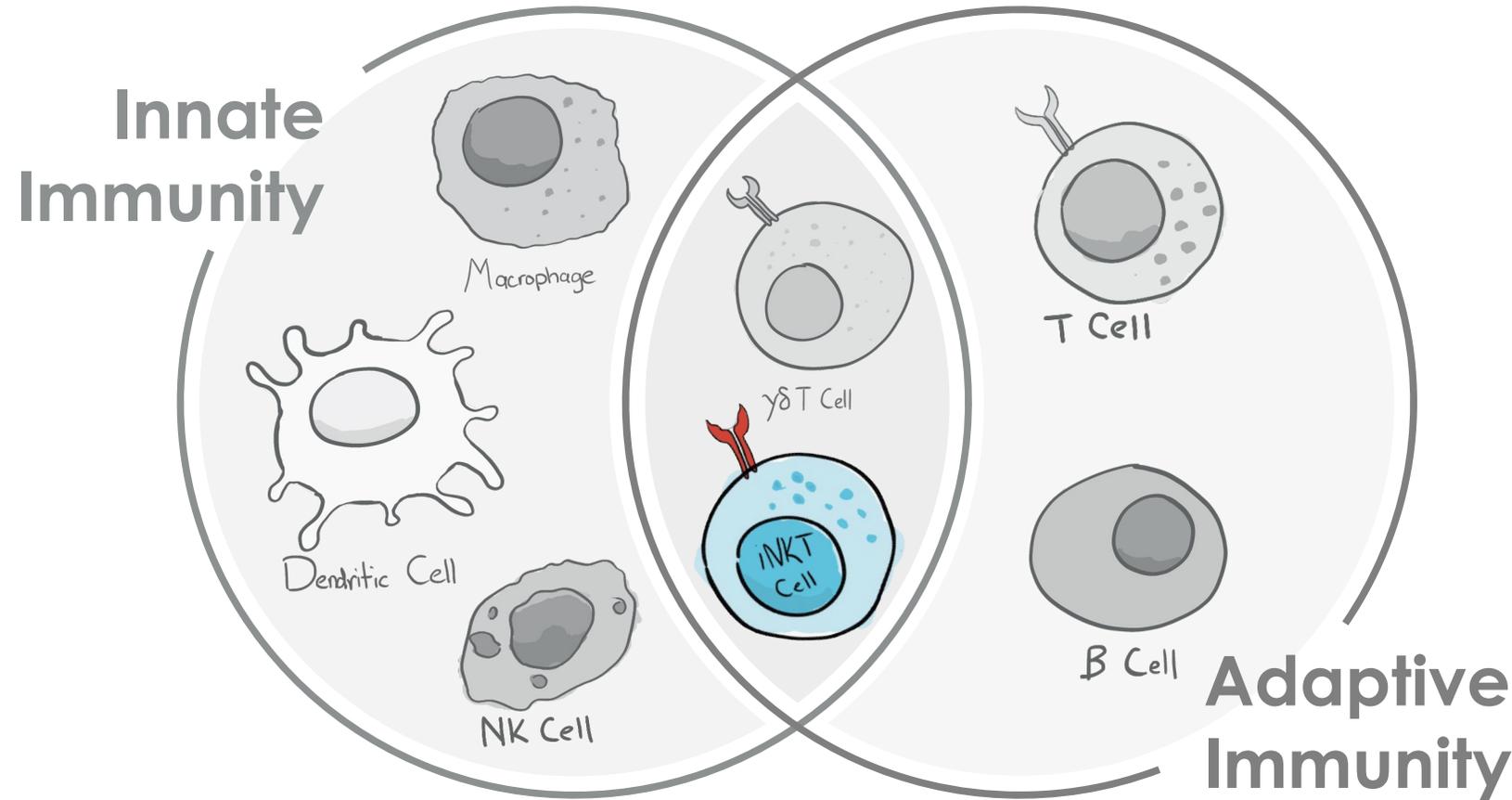
Introducing invariant Natural Killer T (iNKT) cells

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

- Invariant receptor recognizes the same molecule (CD1d) in all people
- Don't cause graft versus host disease (GvHD)¹

Front line of the human immune system

- Bridge the rapid innate & long lasting adaptive immune responses²
- Contain both T cell & NK cell killing mechanisms³
- Naturally target & kill cancers that express CD1d⁴

Multiple anti-cancer properties

- Shape the tumour microenvironment by blocking/killing pro tumour cells (TAMs & MDSCs)^{5,6}
- Infiltrate tumours & secrete signaling molecules to activate other immune cells to kill cancer cells^{6,7}
- CAR-iNKT cells outperform conventional CAR-T cells when tested against blood cancers and solid tumours^{8,9}

1. <https://www.frontiersin.org/journals/immunology/articles/10.3389/fimmu.2024.1436968/full>; 2. <https://link.springer.com/article/10.1007/s00441-010-1023-3>; 3. <https://www.mdpi.com/2218-273X/13/2/348>; 4. <https://www.frontiersin.org/journals/medicine/articles/10.3389/fmed.2022.897750/full>; 5. <https://doi.org/10.1016/j.celrep.2018.02.058>; 6. <https://www.nature.com/articles/s43018-024-00830-0>; 7. <https://pmc.ncbi.nlm.nih.gov/articles/PMC12291068/#B19>; 8. <https://linkinghub.elsevier.com/retrieve/pii/S1535610818303775>; 9. https://www.science.org/doi/10.1126/sciimmunol.abn6563?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%20pubmed



ALA-101 (CAR19-iNKT cells)

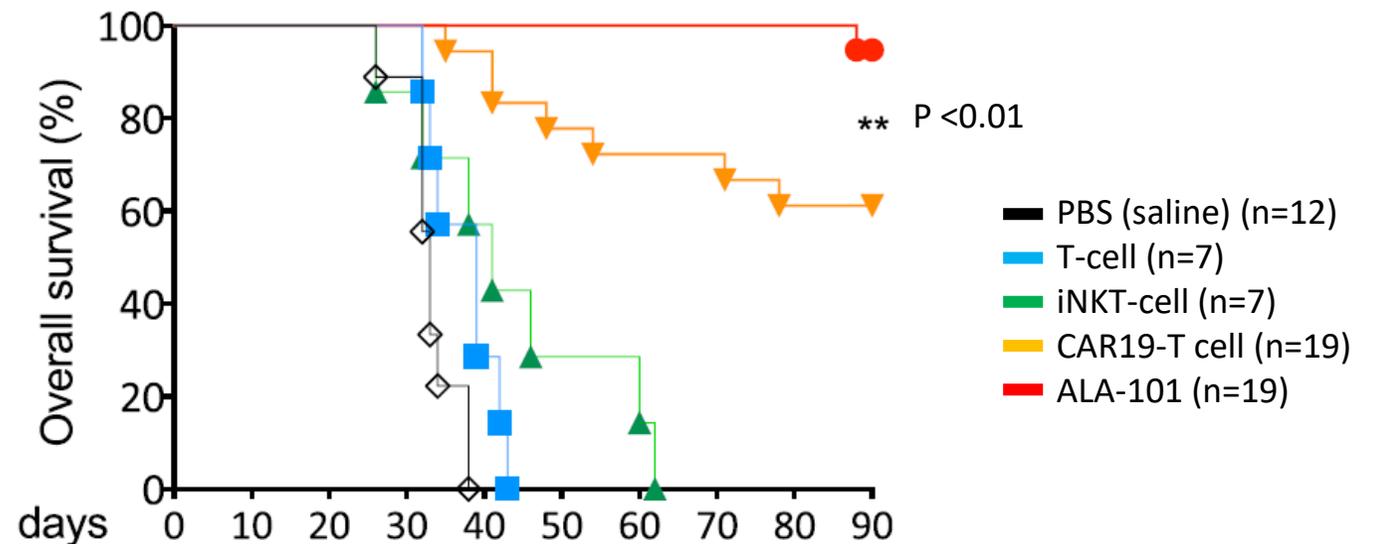
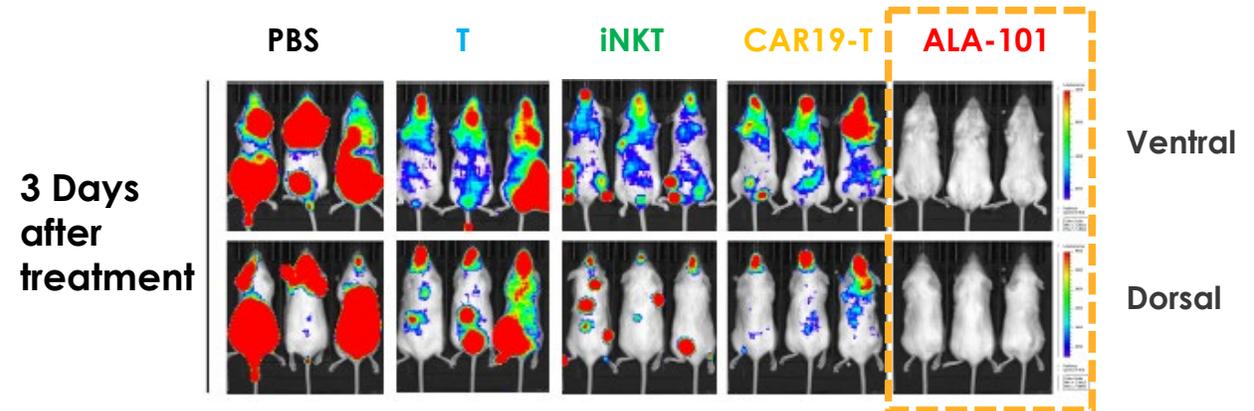
A next generation **off-the-shelf** cell therapy for CD19 expressing cancers

ALA-101 is highly effective at killing cancer cells

In preclinical studies, ALA-101 has superior activity over standard CAR-T therapies

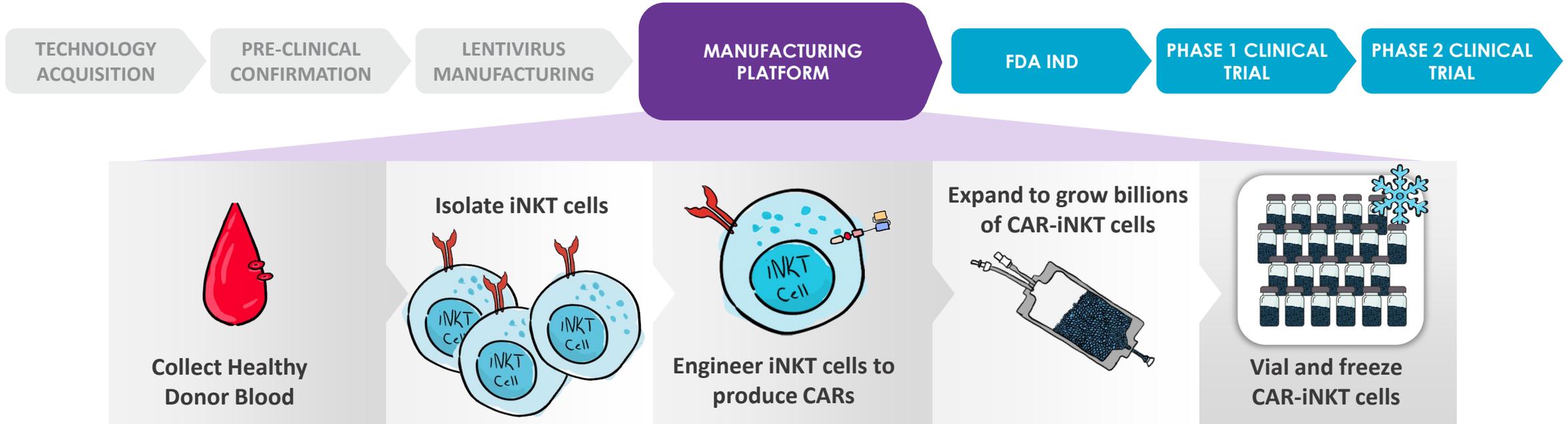
ALA-101 significantly increases survival in mice versus treatment with CAR19-T cells

- Tumour cells producing 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 remain alive
- 1.5x more mice treated with ALA-101 remain 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-producing cancers



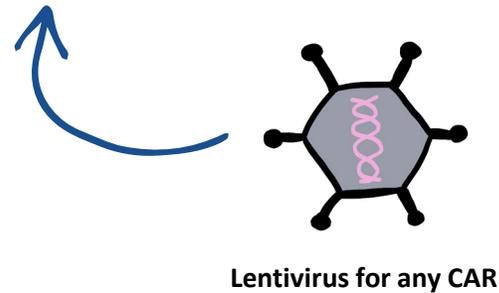
Clinic-ready manufacturing process developed

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



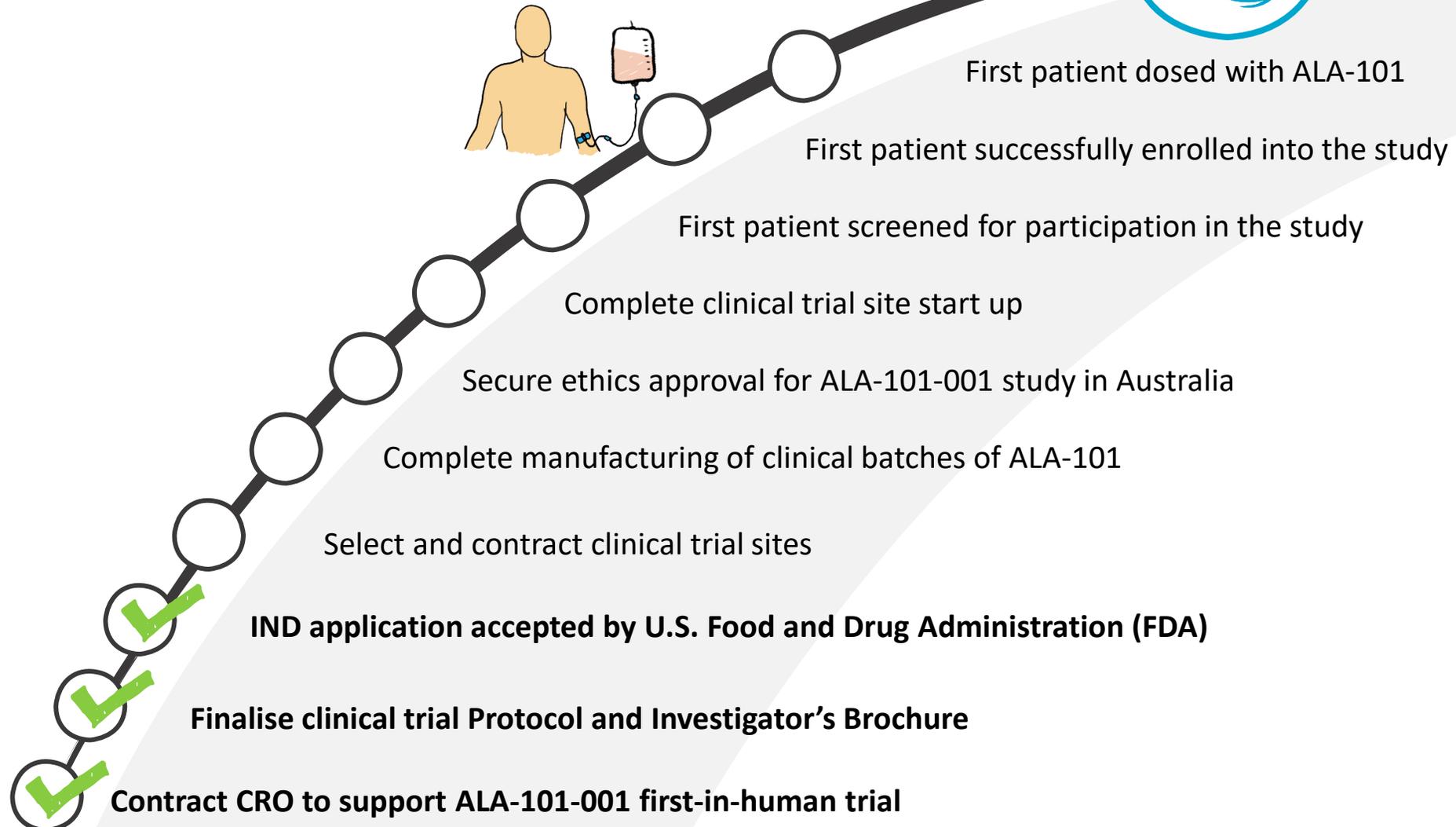
Proprietary cGMP manufacturing process IND-approved for ALA-101

- High yield, >5,000-fold expansion of CAR-iNKT cells
- >99% purity of iNKT cells with a balance of CD4- and CD4+ cells
- Semi-automated, suitable for large-scale production
- Runs now being completed in the GMP suites using GMP reagents
- New knowledge becomes Arovella trade secret and IP
- New products can be created plug and play by substituting the lentivirus



Taking ALA-101 into first-in-human trials

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



ALA-101-001: study design



Part 1

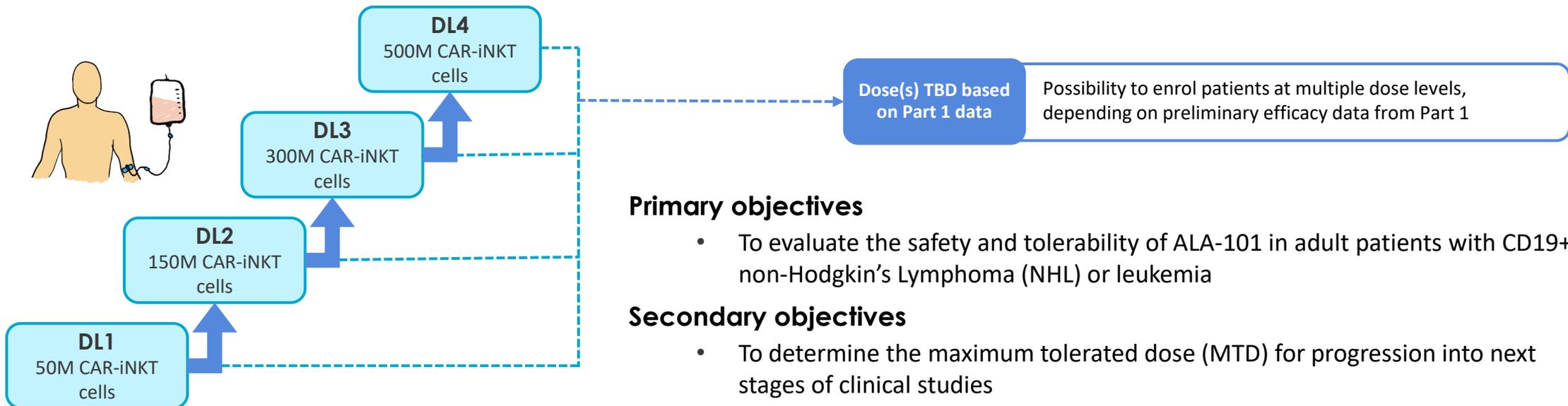
Dose escalation

- 4 dose levels
- 13-21 participants expected*
- CD19+ lymphoma

Part 2

Dose expansion

- Dose levels selected from Part 1
- ~22 additional participants expected*
- CD19+ lymphoma and leukaemia



* Final participant numbers in dose escalation and dose expansion depend on safety profile and the number of doses assessed during dose expansion

Abbreviations: M, million

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>

iNKT cells are well placed to tackle solid tumours

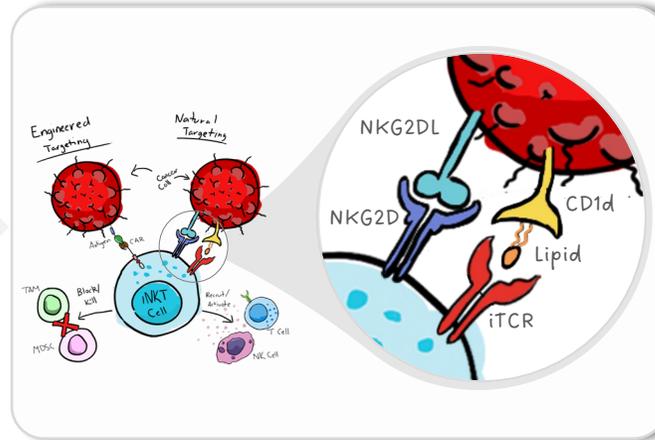
iNKT cells have features that may make them useful for treating solid tumours

Naturally target cancer markers and are prognostic for survival

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

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

iNKT cells can influence the TME, induce cross-priming of other immune cells³, and CAR-iNKT cells have been shown to outperform CAR-T cells when tested using mouse models.⁴



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

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

nature cancer

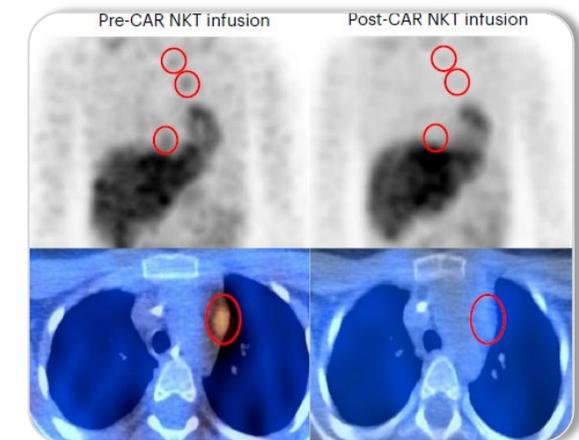
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Article | Published: 01 October 2024

CAR-redirected natural killer T cells demonstrate superior antitumor activity to CAR-T cells through multimodal CD1d-dependent mechanisms

[Xin Zhou](#), [Ying Wang](#), [Zhangqi Dou](#), [Gloria Delfanti](#), [Ourania Tsahouridis](#), [Caroline Marnata Pellegry](#), [Manuela Zingarelli](#), [Gatphan Atassi](#), [Mark G. Woodcock](#), [Giulia Casorati](#), [Paolo Dellabona](#), [William Y. Kim](#), [Linjie Guo](#), [Barbara Savoldo](#), [Ageliki Tsagaratou](#), [Justin Milner](#), [Leonid S. Metelitsa](#) & [Gianpietro Dotti](#) ✉



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



ALA-105 (CLDN18.2 CAR-iNKT)

A clinically validated target
that is expressed in several solid
tumour types

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)

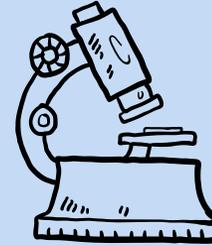
gastroesophageal junction cancer (GEJC)

pancreatic cancer (PC)

esophageal cancer (EC)

ovarian adenocarcinoma (OAC)

lung cancers (LC)



Validated target

with first monoclonal antibody
approved in Japan and the U.S.
in 2024



Gastric cancer

market alone expected to reach

\$10.7 billion by 2031¹



Successfully generated a functional CAR

that targets CLDN18.2

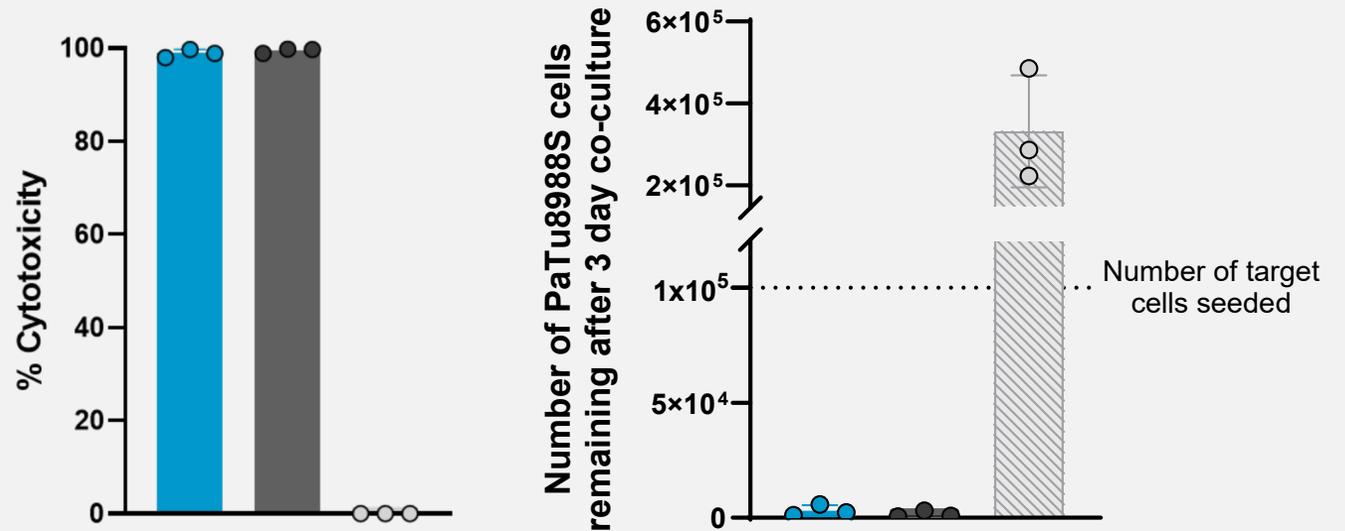
1. <https://www.alliedmarketresearch.com/gastric-cancer-market-A74458#:~:text=The%20global%20gastric%20cancer%20market,cells%20lining%20of%20the%20stomach>

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

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

- The activity of Arovella's newly created CLDN18.2 CAR was tested in T cells for the ability to kill pancreatic cancer cells (PaTu8988S) expressing CLDN18.2 antigen on their surface.
- Arovella's CLDN18.2 CAR demonstrates potent and specific killing of PaTu8988S target cells, equivalent to a control CAR (CT041¹) expected to display robust killing and currently under clinical evaluation, and relative to T cells lacking a CAR (non-transduced T cells).

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

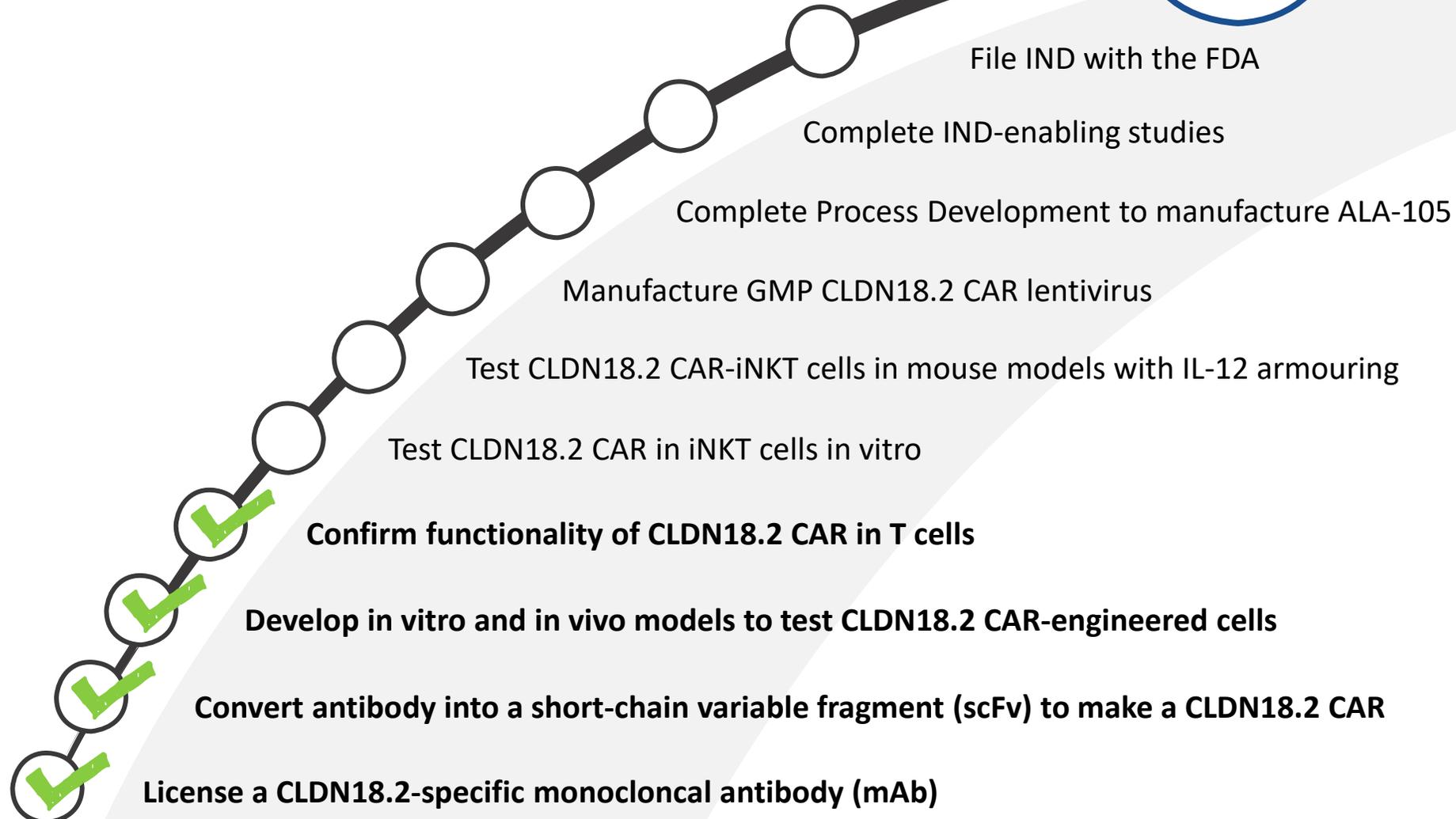


CAR-T cells manufactured from n=3 donors

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

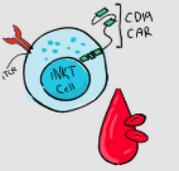
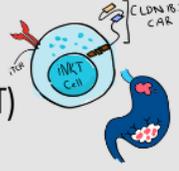
Taking ALA-105 to IND filing

ALA is progressing nonclinical development of ALA-105



Arovella's expanding pipeline



PRODUCT	INDICATION	PRECLINICAL	IND-ENABLING	PHASE 1
ALA-101 (CD19 CAR-iNKT) 	CD19-positive cancers	CD19-positive Lymphoma		
ALA-105 (CLDN18.2 CAR-iNKT) 	CLDN18.2-positive solid tumours	Gastric & Pancreatic Cancers		

Upcoming Milestones

ALA-101
 Commence phase 1 clinical trial for patients with CD19-positive lymphoma and leukaemia

ALA-105
 Generate preclinical data for the CLDN18.2 CAR in iNKT cells with the addition of IL-12-TM armour

Investment highlights

ALA-101 (CAR19-iNKT)

- Clinic ready, following U.S. FDA acceptance of the IND, validating preclinical and manufacturing data
- Phase 1 clinical trials, expected to commence in FY 2026 for CD19-positive lymphoma and leukaemia patients



ALA-105 (CLDN18.2 CAR-iNKT)

- Promising data generated for Arovella's CAR targeting CLDN18.2
- The CAR will be incorporated into iNKT cells and tested using in vitro and animal models



CAR-iNKT – new cancer targets

- Negotiating license agreement with Baylor College of Medicine for iNKT cell IP and new CARs targeting solid tumours
- Continuing to screen across the globe for novel IP to enhance the platform



Corporate highlights

- Strong balance sheet (\$19.4 million¹), funded to early safety and efficacy readouts for the ALA-101 clinical trial
- Uniquely positioned as one of few companies globally developing CAR-iNKT cells for cancer treatment



Financial overview

Financial Snapshot

ASX CODE	ALA
Market capitalisation ¹	\$104.58 million
Shares on issue	1,202.1 million
52-week low / high	\$0.068 / \$0.1950
Cash Balance (31 Dec, 2025)	\$19.4 million

Major Shareholders

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

1. As of 30 January 2025
2. As of 22 August 2025 - Appendix 4E and Annual Report
3. Formerly Merchant Funds Management
4. Holding includes associated entities and parties

ALA Price and Volume - 12 Months¹



ASX:ALA



Thank You

Dr. Michael Baker

CEO & Managing Director

Email: investor@arovella.com

Mobile: +61 403 468 187



Cell therapy deal references

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2. <https://interiusbio.com/press-release/kite-to-acquire-interius-biotherapeutics-to-advance-in-vivo-platform/>
3. <https://news.abbvie.com/2025-06-30-AbbVie-to-Acquire-Capstan-Therapeutics,-Further-Strengthening-Commitment-to-Transforming-Patient-Care-in-Immunology>
4. <https://www.astrazeneca.com/media-centre/press-releases/2025/astrazeneca-to-acquire-esobiotec.html>
5. <https://www.reuters.com/business/healthcare-pharmaceuticals/roche-acquire-us-based-poseida-therapeutics-2024-11-26/>
6. <https://www.astrazeneca.com/media-centre/press-releases/2023/astrazeneca-to-acquire-gracell-furthering-cell-therapy-ambition-across-oncology-and-autoimmune-diseases.html>
7. <https://www.businesswire.com/news/home/20230815091930/en/Precision-BioSciences-Completes-Strategic-Transaction-with-Imugene-for-Azer-Cel-in-Cancer>
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9. <https://www.jnj.com/janssen-enters-worldwide-collaboration-and-license-agreement-with-cellular-biomedicine-group-to-develop-next-generation-car-t-therapies>
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11. <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>
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13. <https://www.adaptimmune.com/investors-and-media/news-center/press-releases/detail/197/adaptimmune-enters-into-a-strategic-collaboration-with>
14. <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>
15. [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)

ASX:ALA



arōvella
T H E R A P E U T I C S

Investor Presentation

Non-deal roadshow – February 2026

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Arovella's Investment Highlights

A high-angle photograph of a swimmer in a pool, viewed from above. The swimmer is in the middle of a stroke, with their arms extended forward and their head above water. The pool is blue, and there are lane lines visible. The swimmer is wearing a black cap and dark swim trunks. The water is splashing around the swimmer's arms.

U.S. FDA IND Accepted for ALA-101¹

U.S. FDA IND secured for ALA-101, and anticipate commencing phase 1 clinical trials in FY 2026 for CD19-positive blood cancers

Addressing Key Unmet Need

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

Strategic Acquisitions

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

Off-the-Shelf iNKT Cell Platform

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

Clinic-ready Manufacturing Process

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

Strong Leadership Group

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

1. Date is indicative only, based on current estimates and subject to change.

IND accepted by U.S. Food and Drug Administration (FDA)

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

Key operational and regulatory milestone



Provides regulatory validation of ALA-101's preclinical package, manufacturing process, and clinical development plan



Enables Arovella to conduct its phase 1 trial in Australia and the U.S. for patients with CD19-positive lymphoma and leukaemia



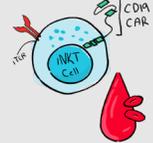
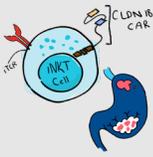
Ended December quarter at \$19.4 million, enough to reach preliminary clinical safety and efficacy readouts for ALA-101



Provides the framework for future IND applications targeting solid tumours, including ALA-105, and new CARs

Arovella's path to patient



PRODUCT	TECHNOLOGY ACQUISITION	PRE-CLINICAL CONFIRMATION	LENTIVIRUS MANUFACTURING	MANUFACTURING PLATFORM	FDA IND	PHASE 1 CLINICAL TRIAL ¹	PHASE 2 CLINICAL TRIAL
CD19 CAR-iNKT Lymphoma ALA-101 	✓	✓	✓	✓	✓	FY 2026	
CLDN18.2 CAR-iNKT Gastric cancer and pancreatic cancer ALA-105 	✓			✓			
CAR-iNKT Other cancers (i.e. GD2, GPC3) 				✓			


 The IND for **ALA-101** has been **accepted by the FDA** to commence first-in-human clinical trials


 Arovella's CLDN18.2 CAR demonstrates **robust killing** of pancreatic cancer cell lines expressing CLDN18.2


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

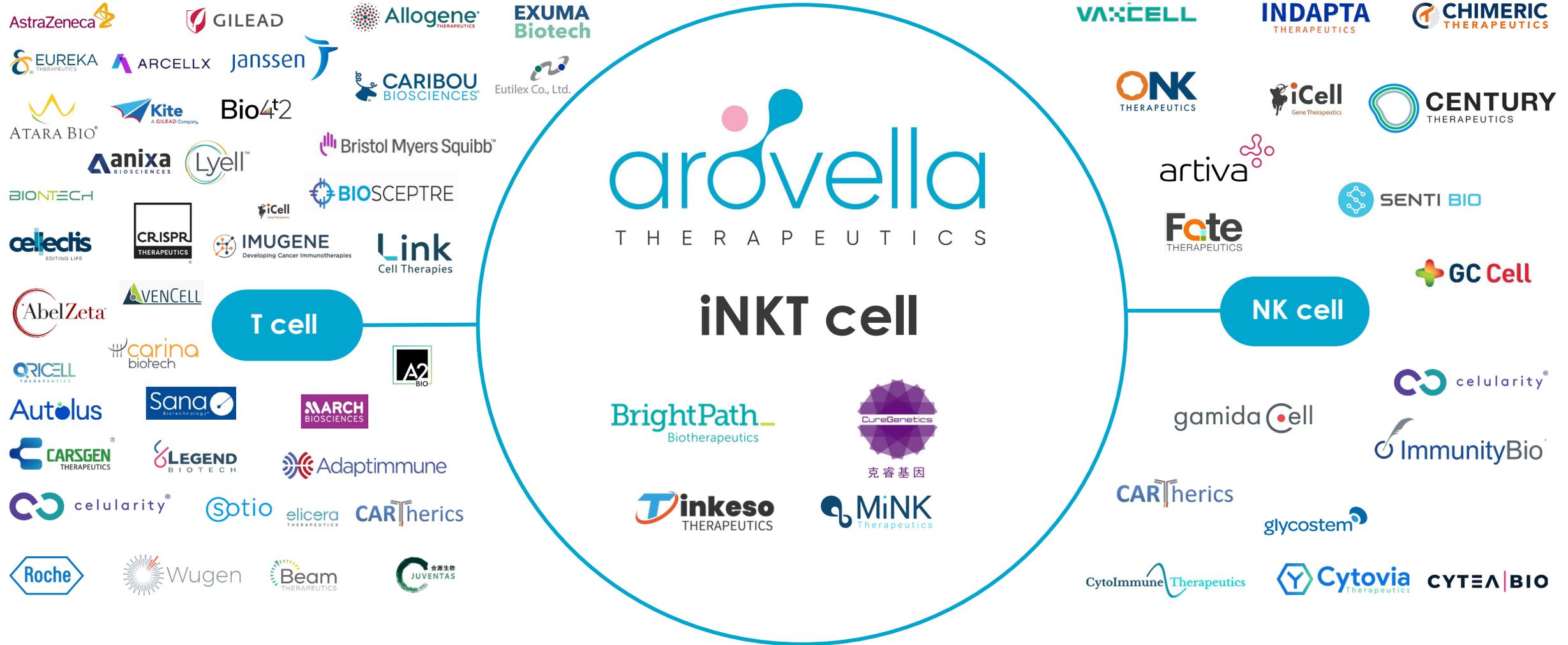
Recent cell therapy transactions¹

Date	Type of deal	Acquirer/Licensee	Target/Licensor	Cell Type	Stage	Upfront (US\$M)	Milestones (US\$M)	Total deal value (US\$M)
Oct-25	Acquisition	 Bristol Myers Squibb	 ORBITAL THERAPEUTICS	In vivo CAR	Preclinical ²	\$1,500	\$0	\$1,500
Aug-25	Acquisition	 Kite A GILEAD Company	 interius	In vivo CAR	Phase 1	\$350	\$0	\$350
Jun-25	Acquisition	 abbvie	 capstantx™	In vivo CAR	Phase 1	\$2,100	\$0	Up to \$2,100
Mar-25	Acquisition	 AstraZeneca	 EsoBiotec	In vivo CAR	Phase 1	\$425	\$575	\$1,000
Nov-24	Acquisition	 Roche	 POSEIDA THERAPEUTICS	Allo T cell	Phase 1	~\$1,038	~\$462	\$1,500
Dec-23	Acquisition	 AstraZeneca	 GRACELL	T Cell	Phase 1b	\$1,000	\$200	\$1,200
Aug-23	Licence 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	
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	 Kite A GILEAD Company	 APPIA BIO	iNKT Cell	Preclinical	undisclosed	undisclosed	\$875
May-21	Acquisition	 Athenex	 kuur THERAPEUTICS	iNKT Cell	Phase 1	\$70	\$115	\$185

1. See the last slide for deal references; 2. Preclinical data in non-human primates - <https://www.orbitaltx.com/orbital-therapeutics-presents-non-human-primate-data-for-in-vivo-car-t-therapy-with-potential-best-in-class-profile-for-autoimmune-disease>; 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

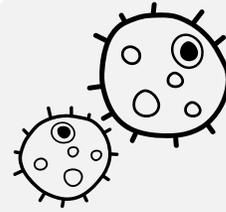
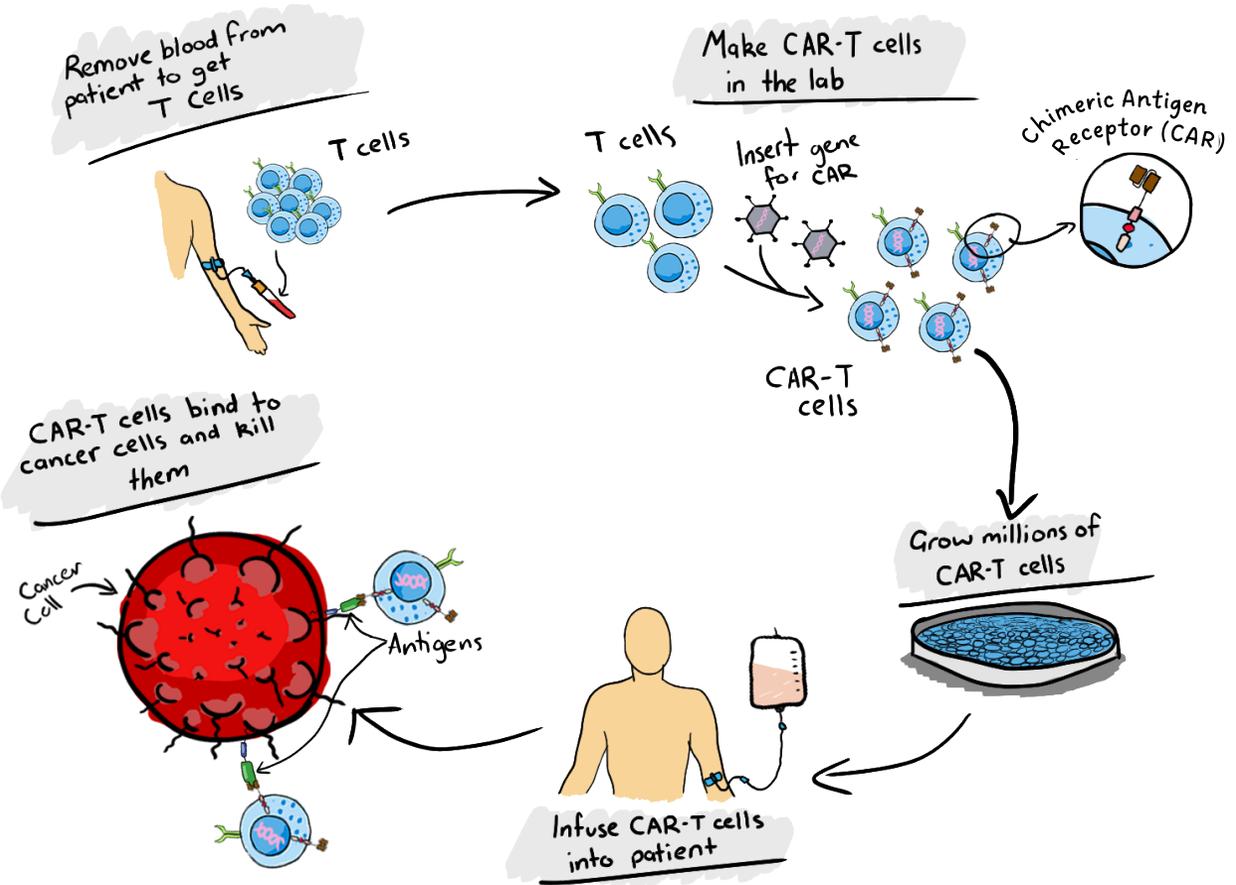




About CAR-T cells

How original CAR-T cell therapies work

CAR-T cell therapy is personalised medicine



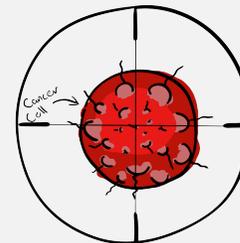
T cells = immune cell

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.

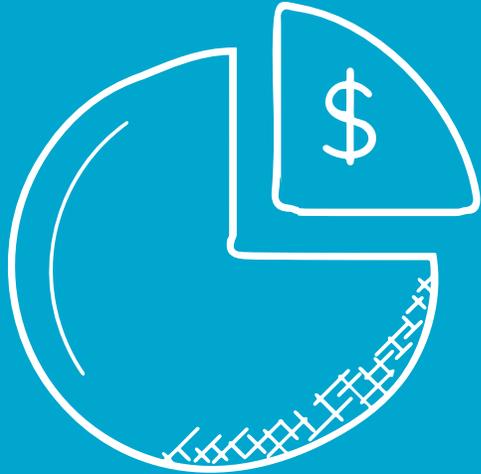


CAR-T cells find & kill tumour cells

CAR-T cells are administered to the patient to find and kill the cancer cells. Once the CAR recognizes and binds to the target antigen on the cancer cell, the CAR-T cell is activated to kill the cancer cell.

Cell Therapy has revolutionised blood cancer treatment

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



The CAR-T market is expected to reach **\$15.2 billion** by 2035¹

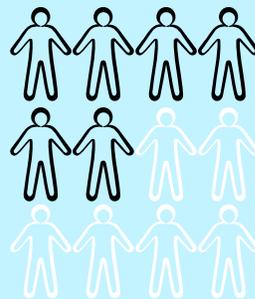


Cure

CAR-T cells have demonstrated ability to cure haematological cancers



Strong Sales



40-60%

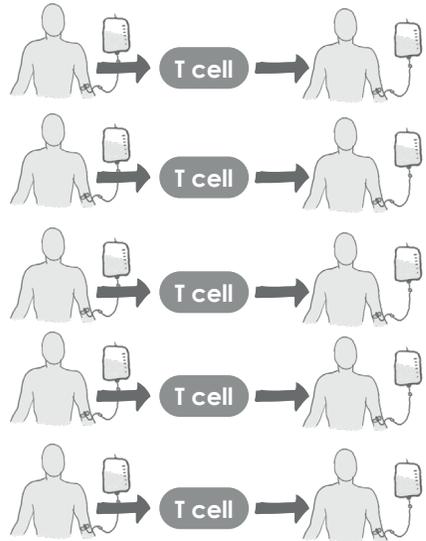
Patients relapse post-CAR-T therapy²

Product	Approval Year	2024 Revenue
 YESCARTA (axicabtagene ciloleucel)	2017	US\$1570m ³
 KYMRIAH (tisagenlecleucel)	2017	US\$442m ⁴
 Abecma (idecabtagene vicleucel)	2021	US\$242m ⁵

- <https://www.businesswire.com/news/home/20250210311887/en/CAR-T-Cell-Therapy-Market-Industry-Trends-and-Global-Forecasts-to-2035-CD19-and-BCMA-Have-Emerged-as-the-Most-Popular-Target-Antigens---ResearchAndMarkets.com>
- Zinzi et al., 2023 Pharmacological Research - 10.1016/j.phrs.2023.106742
- <https://www.gilead.com/news/news-details/2025/gilead-sciences-announces-fourth-quarter-and-full-year-2024-financial-results>.
- https://www.novartis.com/sites/novartis_com/files/2025-01-interim-financial-report-en.pdf
- <https://ir.2seventybio.com/news-releases/news-release-details/2seventy-bio-reports-preliminary-full-year-us-abecma-sales-and>

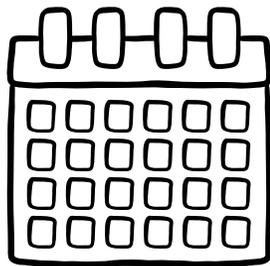
Current CAR-T technology challenges

One CAR-T product **only** treats the patient who supplied the T cells



Each manufacturing batch is **patient-specific**

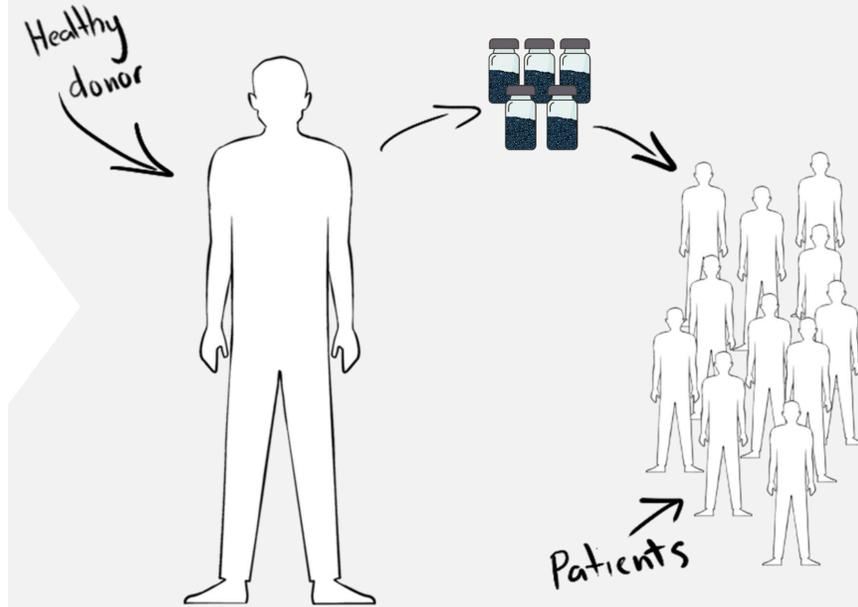
Patient must wait **3-4 weeks** for therapy



-  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

ALA's solution:

One CAR-iNKT batch from **a healthy donor** treats multiple patients



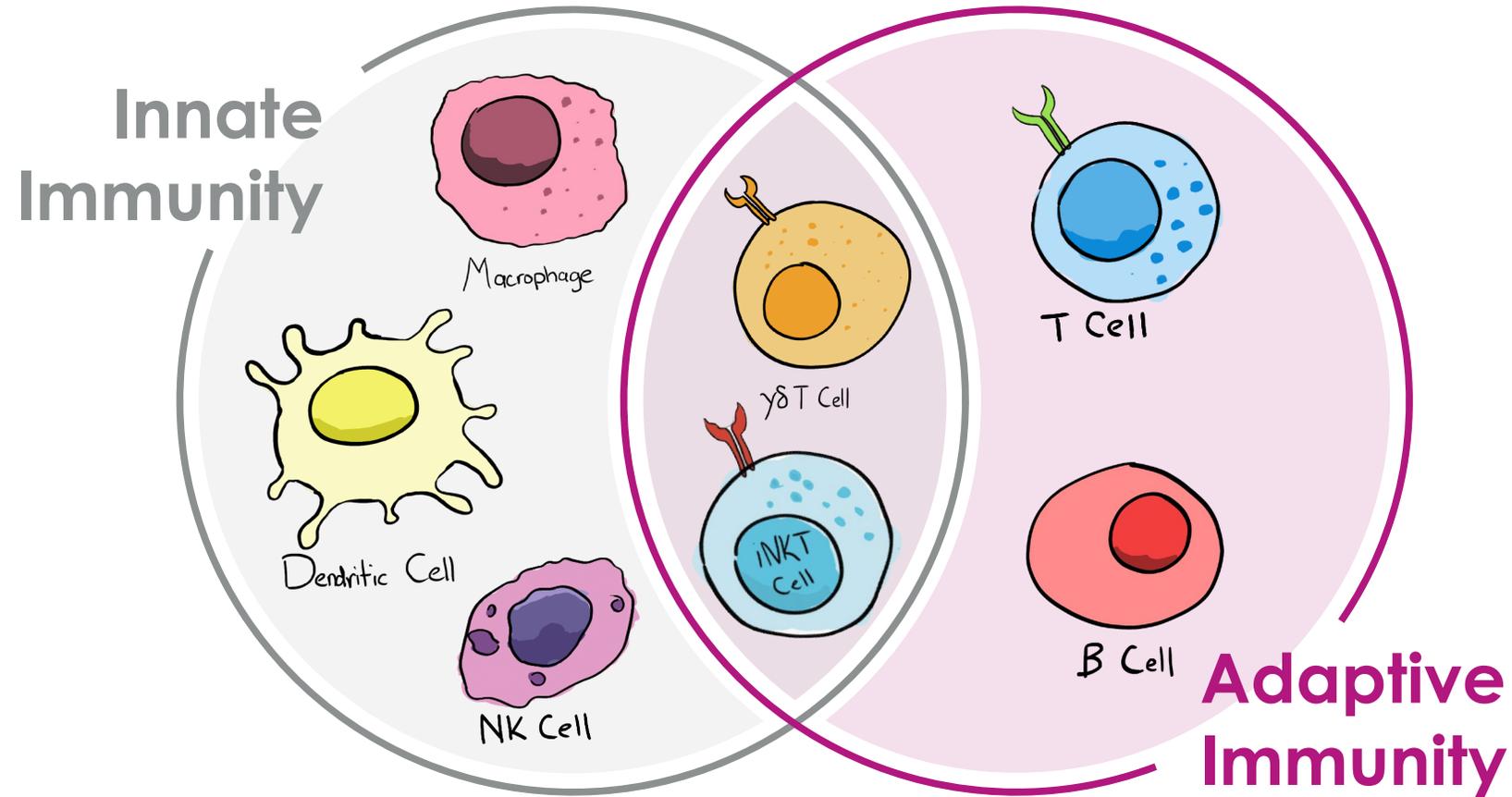
1 week

Patients ready to dose within 1 week



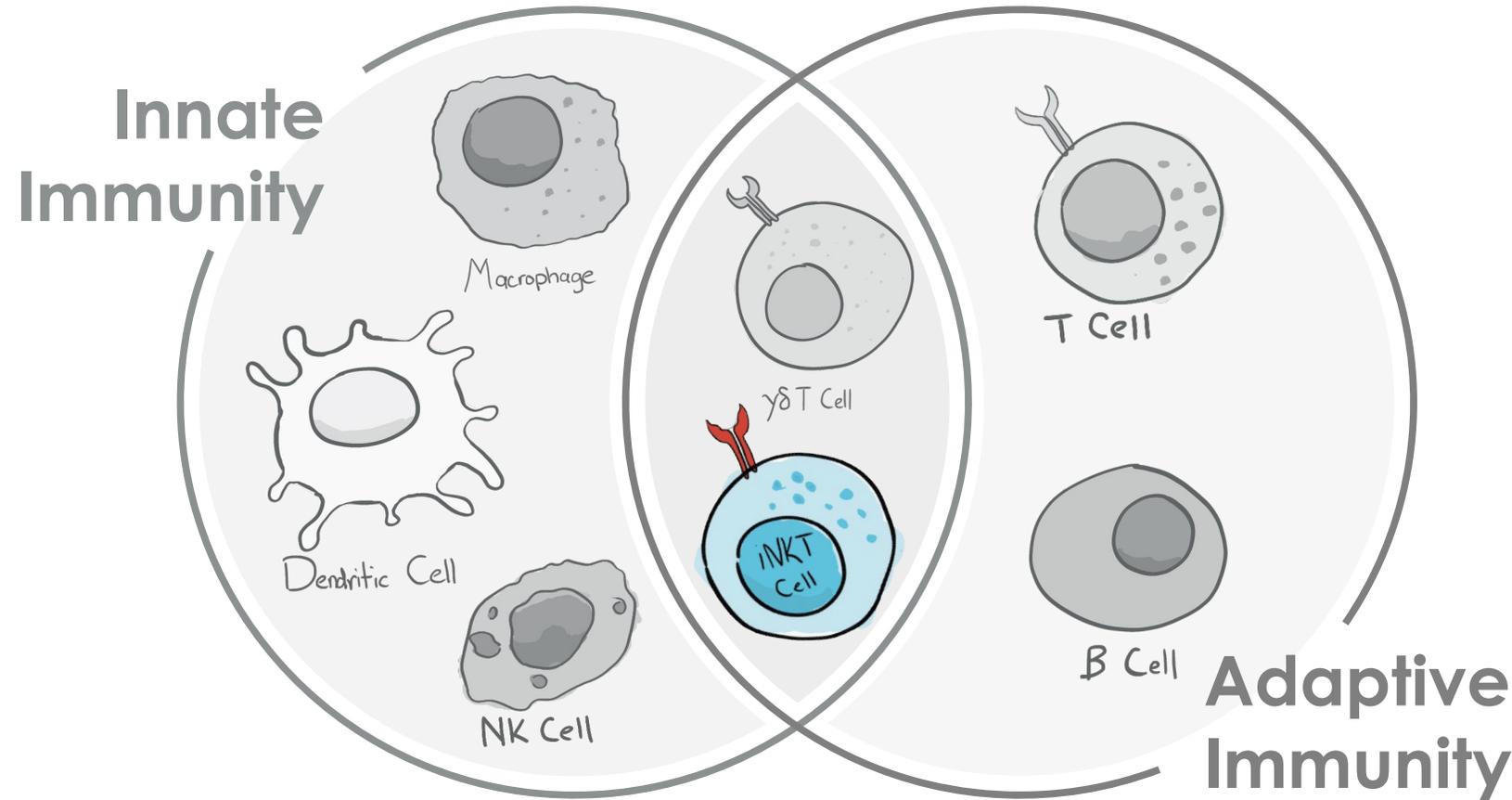
Introducing invariant Natural Killer T (iNKT) cells

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

- Invariant receptor recognizes the same molecule (CD1d) in all people
- Don't cause graft versus host disease (GvHD)¹

Front line of the human immune system

- Bridge the rapid innate & long lasting adaptive immune responses²
- Contain both T cell & NK cell killing mechanisms³
- Naturally target & kill cancers that express CD1d⁴

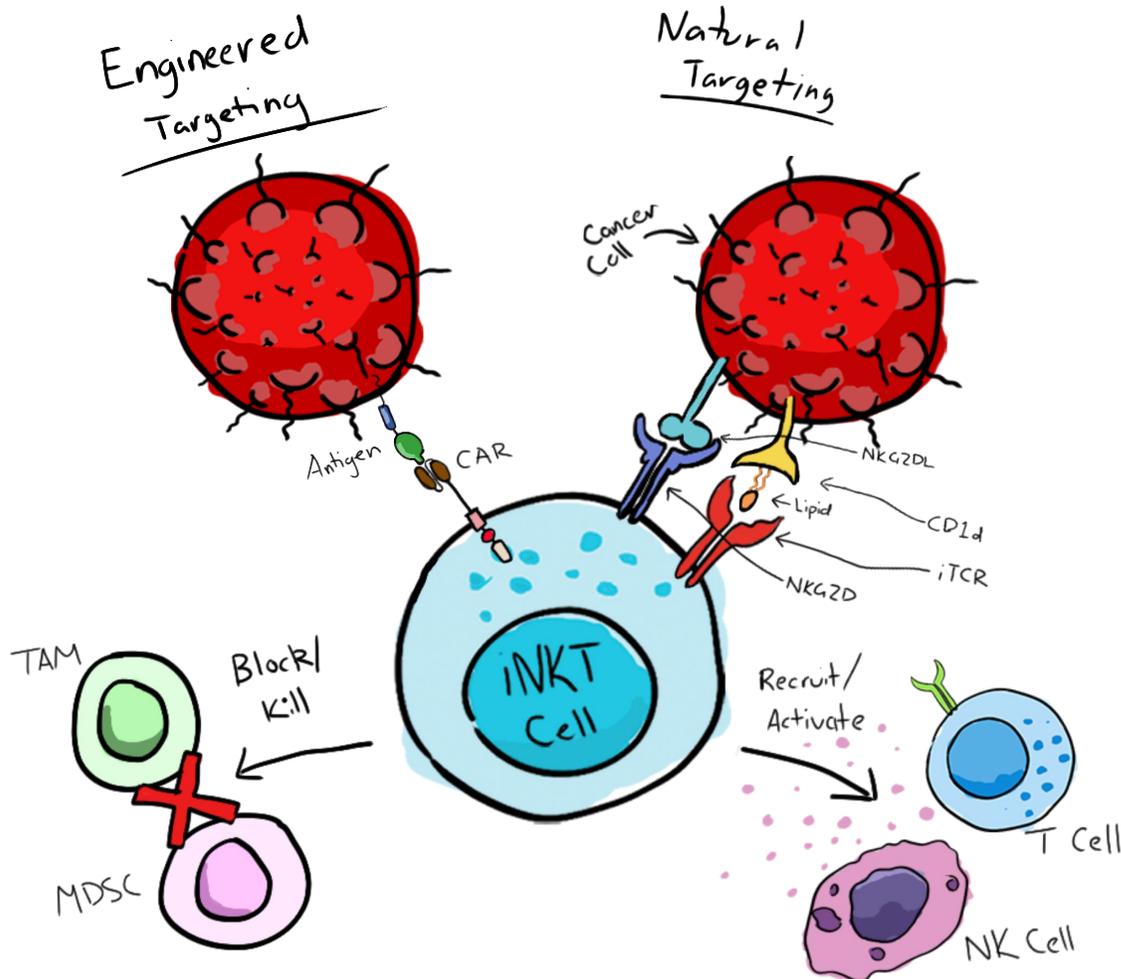
Multiple anti-cancer properties

- Shape the tumour microenvironment by blocking/killing pro tumour cells (TAMs & MDSCs)^{5,6}
- Infiltrate tumours & secrete signaling molecules to activate other immune cells to kill cancer cells^{6,7}
- CAR-iNKT cells outperform conventional CAR-T cells when tested against blood cancers and solid tumours^{8,9}

1. <https://www.frontiersin.org/journals/immunology/articles/10.3389/fimmu.2024.1436968/full>; 2. <https://link.springer.com/article/10.1007/s00441-010-1023-3>; 3. <https://www.mdpi.com/2218-273X/13/2/348>; 4. <https://www.frontiersin.org/journals/medicine/articles/10.3389/fmed.2022.897750/full>; 5. <https://doi.org/10.1016/j.celrep.2018.02.058>; 6. <https://www.nature.com/articles/s43018-024-00830-0>; 7. <https://pmc.ncbi.nlm.nih.gov/articles/PMC12291068/#B19>; 8. <https://linkinghub.elsevier.com/retrieve/pii/S1535610818303775>; 9. https://www.science.org/doi/10.1126/sciimmunol.abn6563?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%20pubmed

CAR-iNKT cells have multiple ways to kill cancer cells

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



Multiple ways to kill cancer cells

1

ENGINEERED TARGETING

Via the CAR: Specific target depending on tumour type

2

NATURAL TARGETING

Via the NKG2D pathway: NKG2D ligands are upregulated in cancer cells

Via lipid-bound CD1d: Several cancers naturally express CD1d

3

REMODULATE THE TUMOUR MICROENVIRONMENT

By blocking or killing tumour associated macrophages and myeloid derived suppressor cells

4

ACTIVATE T AND NK CELLS

iNKT cells release cytokines that cause activation of cytotoxic T and NK cells to start eliminating tumour cells and promote the cross-priming of T cells



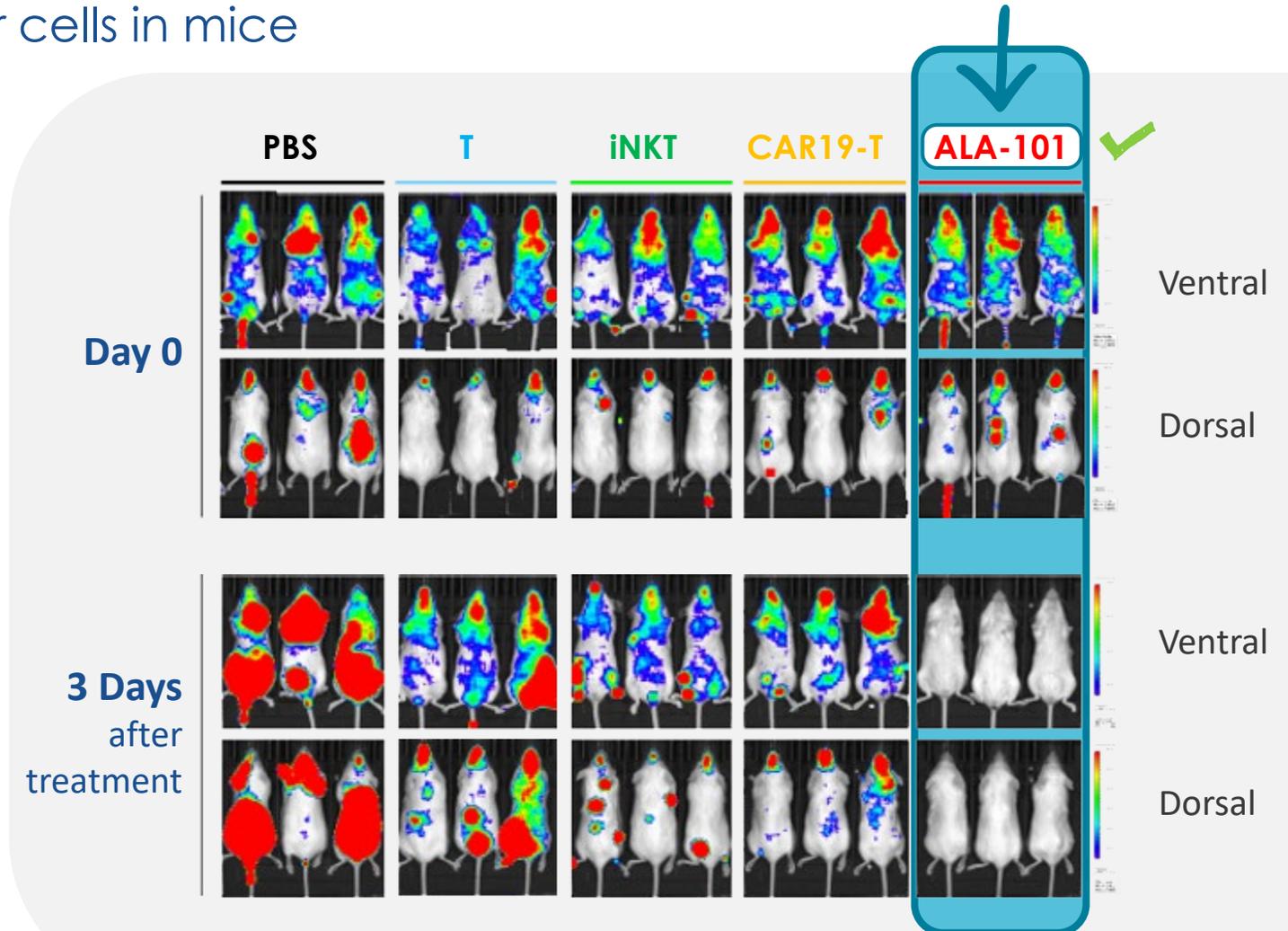
ALA-101 (CAR19-iNKT cells)

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

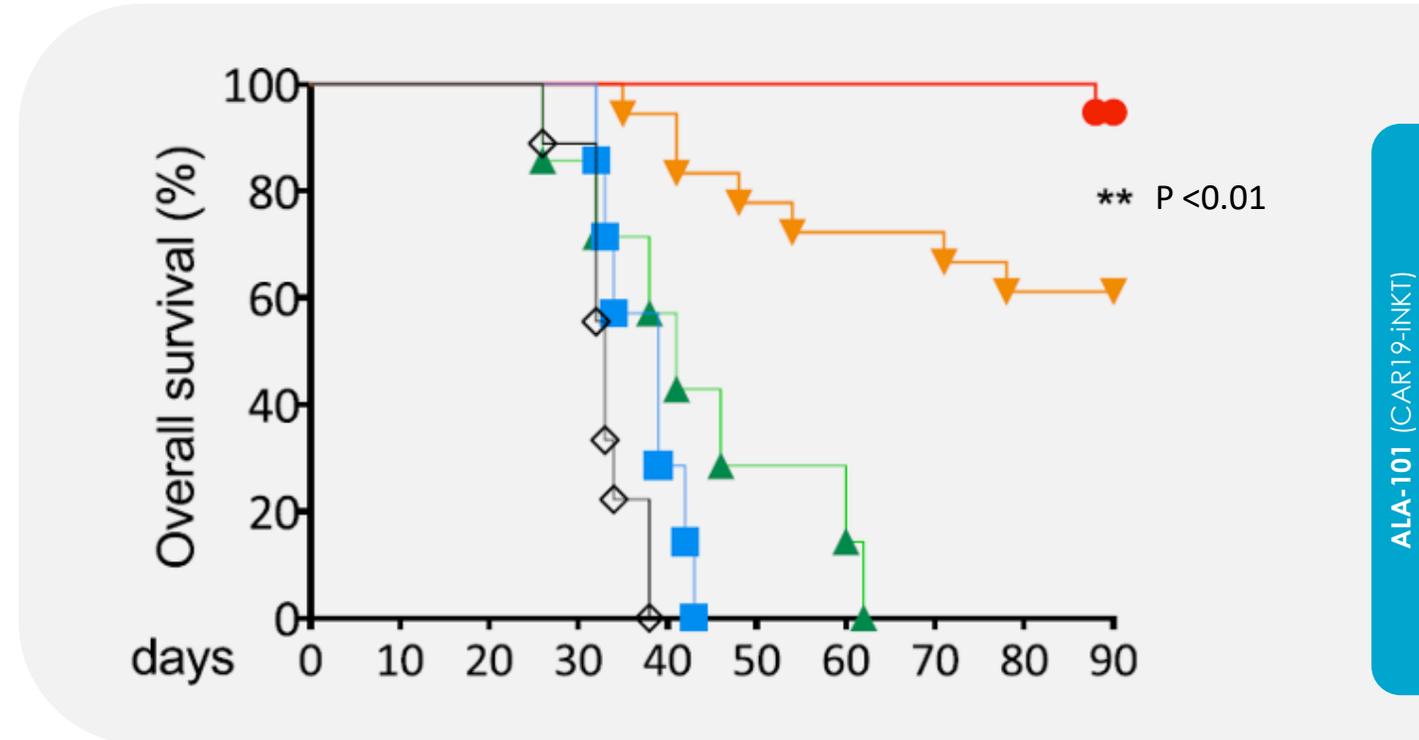


Rotolo *et al.*, Cancer Cell (2018)

ALA-101: next generation cell therapy

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

- Tumour cells positive for **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-positive cancers



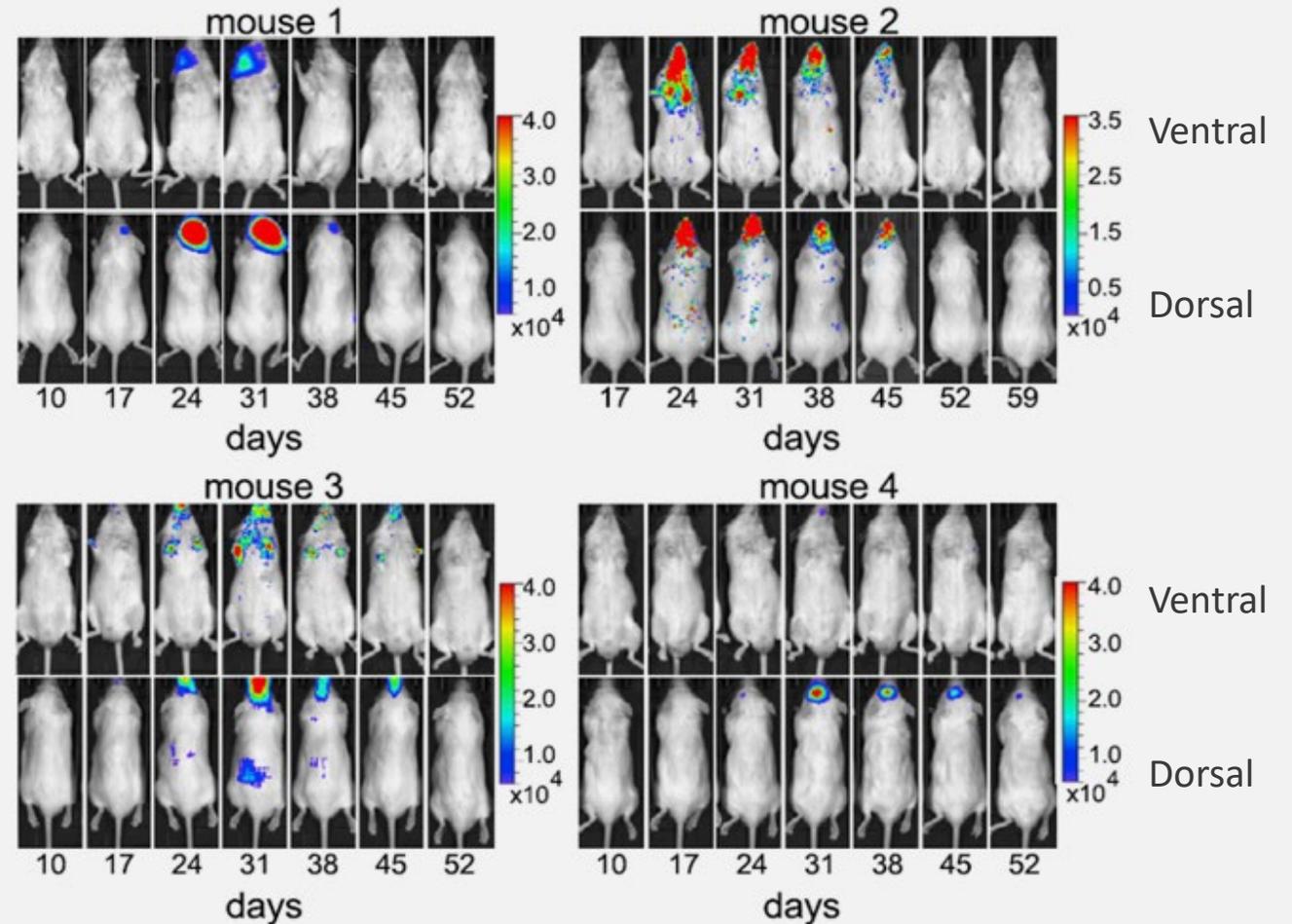
- PBS (saline) (n=12)
- T cell (n=7)
- iNKT cell (n=7)
- CAR19-T cell (n=19)
- ALA-101 (n=19)

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

ALA-101: spontaneous secondary remission

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

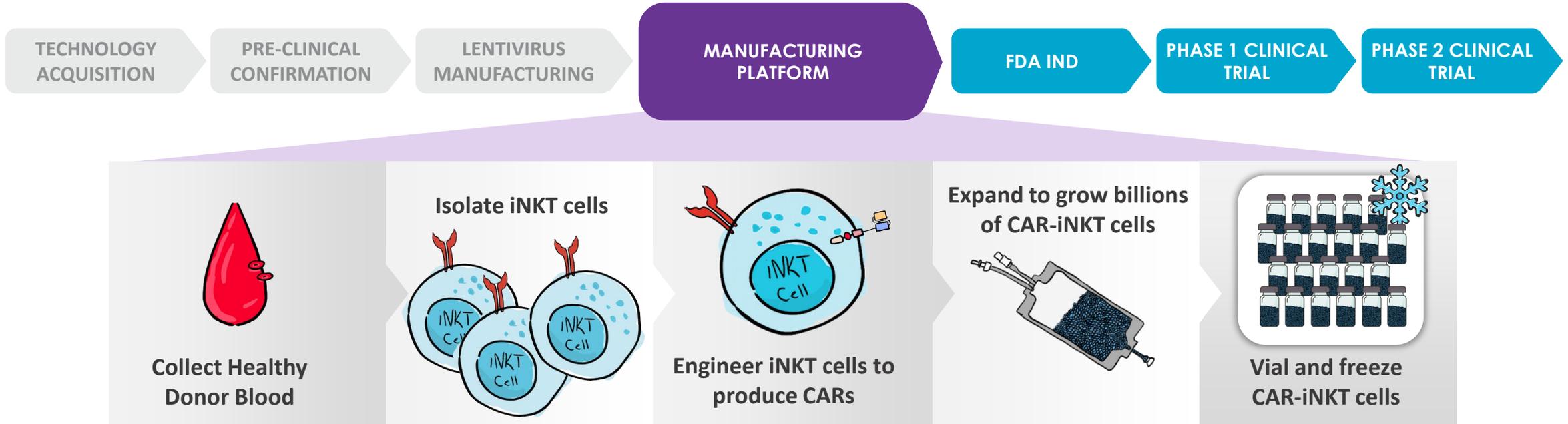
- Four mice treated with ALA-101 had the cancer return to the brain
- In all four mice, the cancer was eliminated a second time with no additional dosing
- This provides evidence that CAR19-iNKT cells can survive and continue to protect against cancer cells in vivo
- Potential to use ALA-101 to treat central nervous system lymphoma or brain metastases



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

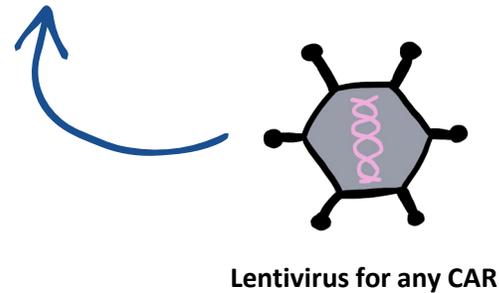
Clinic-ready manufacturing process developed

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



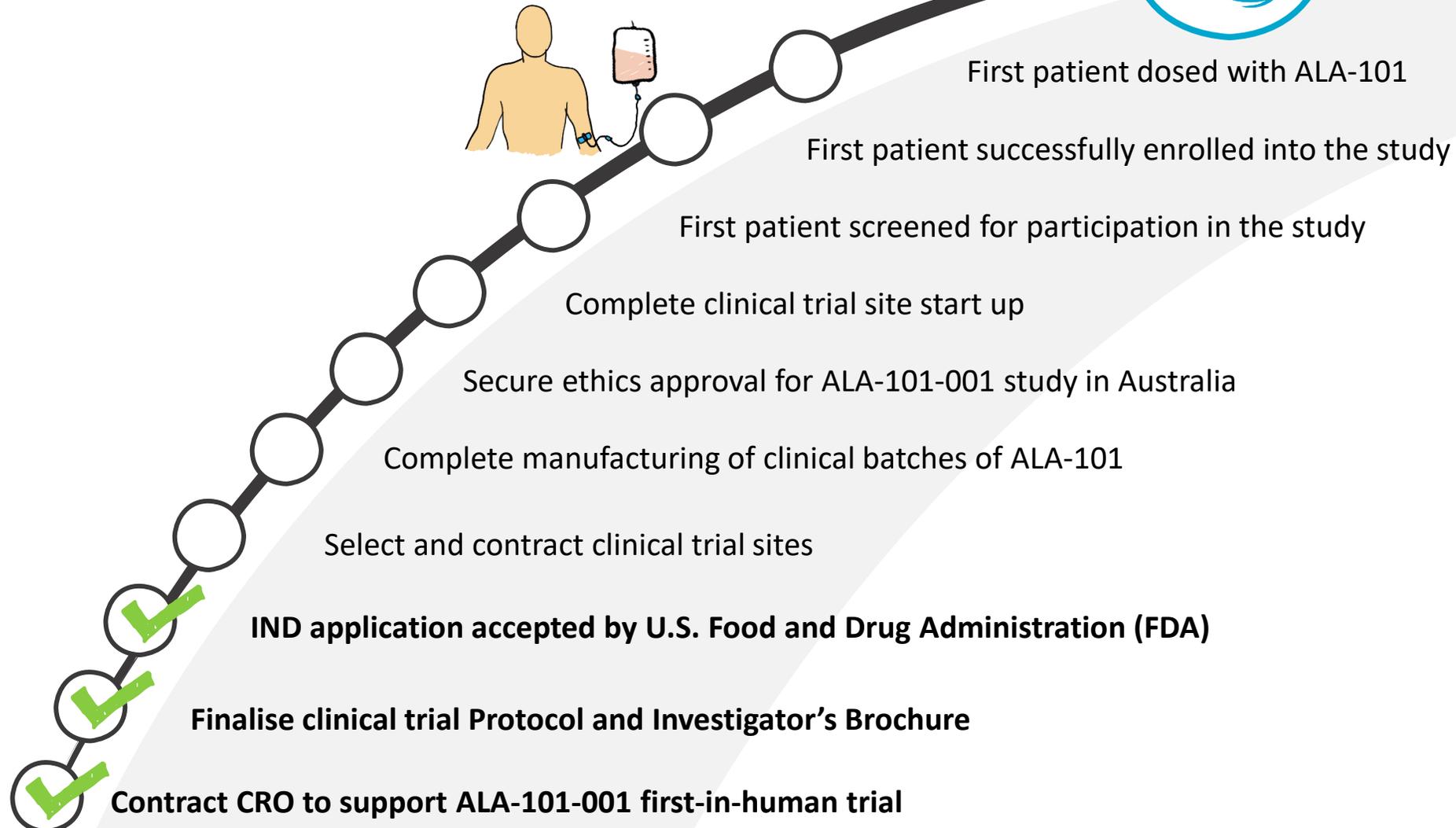
Proprietary cGMP manufacturing process IND-approved for ALA-101

- **High yield**, >5,000-fold expansion of CAR-iNKT cells
- >99% **purity** of iNKT cells with a **balance of CD4- and CD4+ cells**
- **Semi-automated**, suitable for **large-scale production**
- Runs now being completed in the **GMP suites** using **GMP reagents**
- New knowledge becomes Arovella **trade secret** and **IP**
- New products can be **created plug and play** by substituting the lentivirus



Taking ALA-101 into first-in-human trials

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



ALA-101-001: study design



Part 1

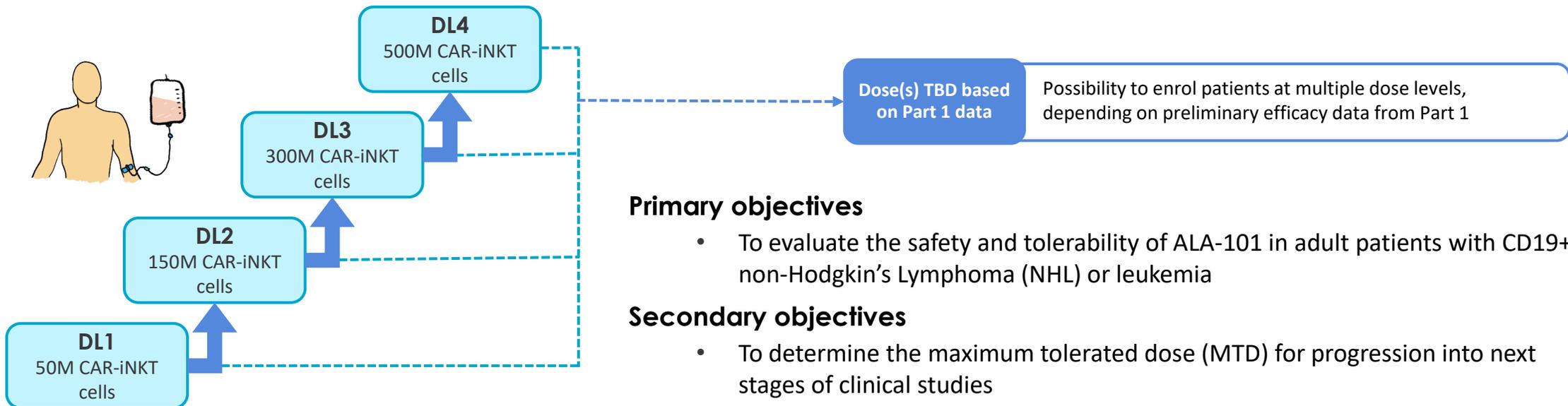
Dose escalation

- 4 dose levels
- 13-21 participants expected*
- CD19+ lymphoma

Part 2

Dose expansion

- Dose levels selected from Part 1
- ~22 additional participants expected*
- CD19+ lymphoma and leukaemia



* Final participant numbers in dose escalation and dose expansion depend on safety profile and the number of doses assessed during dose expansion

Abbreviations: M, million

iNKT cells to target solid tumours

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

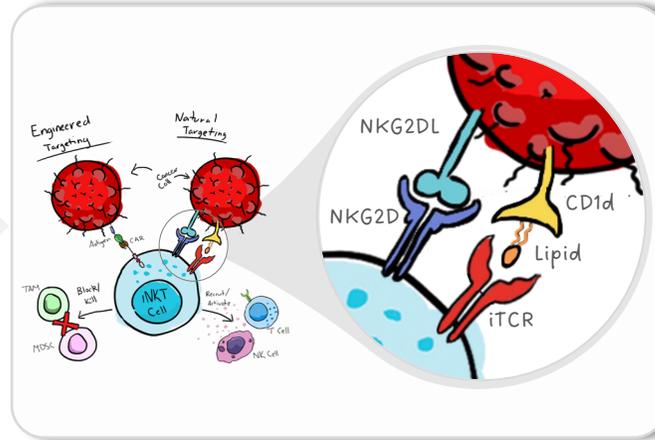
1. <https://www.cancer.gov/types/common-cancers>

iNKT cells are well placed to tackle solid tumours

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

Naturally target cancer markers and are prognostic for survival

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



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

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

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

iNKT cells can influence the TME, induce cross-priming of other immune cells³, and CAR-iNKT cells have been shown to outperform CAR-T cells when tested using mouse models.⁴

nature cancer

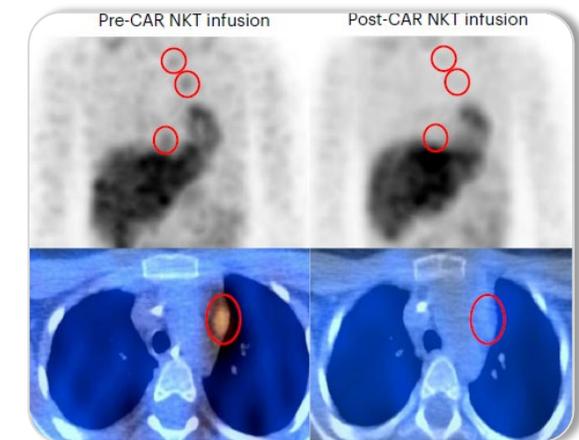
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Article | Published: 01 October 2024

CAR-redirected natural killer T cells demonstrate superior antitumor activity to CAR-T cells through multimodal CD1d-dependent mechanisms

[Xin Zhou](#), [Ying Wang](#), [Zhangqi Dou](#), [Gloria Delfanti](#), [Ourania Tsahouridis](#), [Caroline Marnata Pellegry](#), [Manuela Zingarelli](#), [Gatphan Atassi](#), [Mark G. Woodcock](#), [Giulia Casorati](#), [Paolo Dellabona](#), [William Y. Kim](#), [Linjie Guo](#), [Barbara Savoldo](#), [Ageliki Tsagaratou](#), [Justin Milner](#), [Leonid S. Metelitsa](#) & [Gianpietro Dotti](#) ✉



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



ALA-105 (CLDN18.2 CAR-iNKT)

A clinically validated target
that is expressed in several solid
tumour types

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)

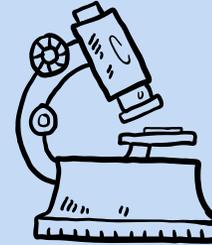
gastroesophageal junction cancer (GEJC)

pancreatic cancer (PC)

esophageal cancer (EC)

ovarian adenocarcinoma (OAC)

lung cancers (LC)



Validated target

with first monoclonal antibody
approved in Japan and the U.S.
in 2024



Gastric cancer

market alone expected to reach

\$10.7 billion by 2031¹



Successfully generated a functional CAR

that targets CLDN18.2

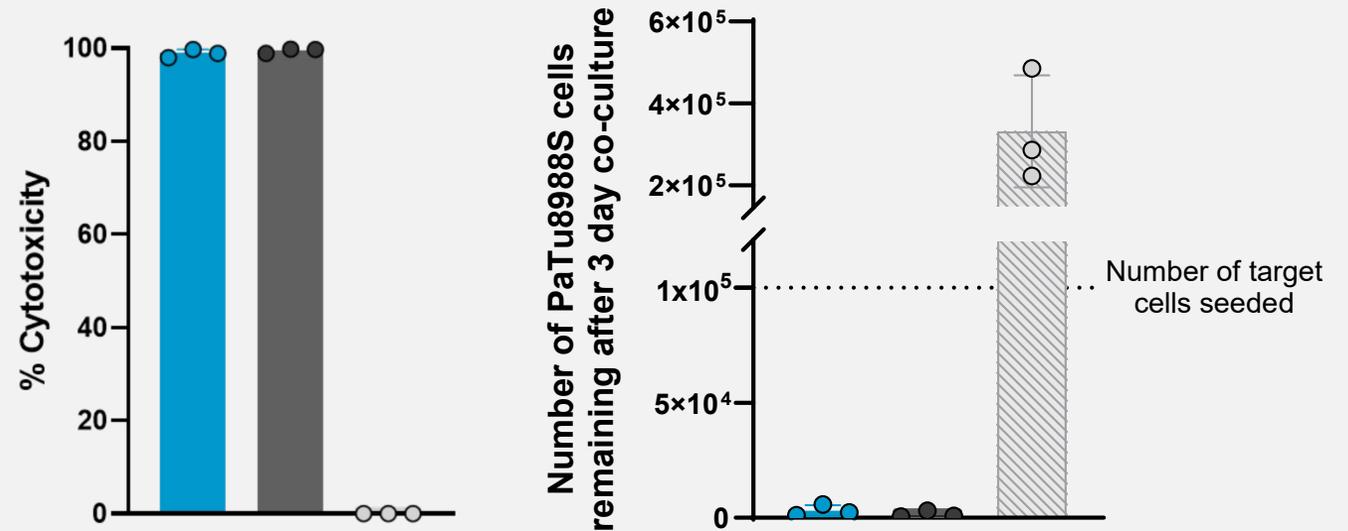
1. <https://www.alliedmarketresearch.com/gastric-cancer-market-A74458#:~:text=The%20global%20gastric%20cancer%20market,cells%20lining%20of%20the%20stomach>

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

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

- The activity of Arovella's newly created CLDN18.2 CAR was tested in T cells for the ability to kill pancreatic cancer cells (PaTu8988S) expressing CLDN18.2 antigen on their surface.
- Arovella's CLDN18.2 CAR demonstrates potent and specific killing of PaTu8988S target cells, equivalent to a control CAR (CT041¹) expected to display robust killing and currently under clinical evaluation, and relative to T cells lacking a CAR (non-transduced T cells).

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

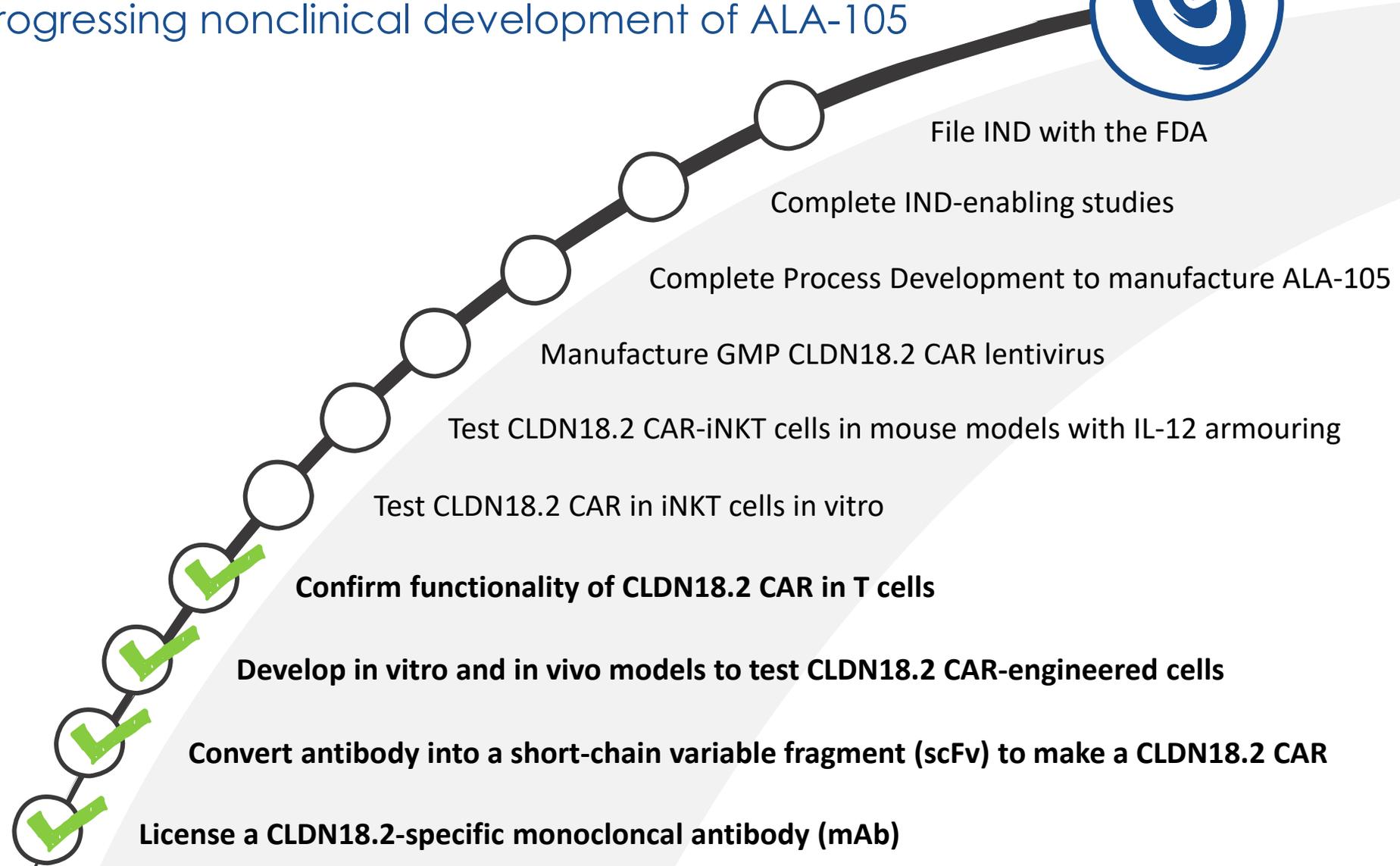


CAR-T cells manufactured from n=3 donors

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

Taking ALA-105 to IND filing

ALA is progressing nonclinical development of ALA-105





IL-12-TM (Solid Tumors)

“Armouring” CAR-iNKT cells



“Armouring” CAR-iNKT cells

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

IL-12-TM

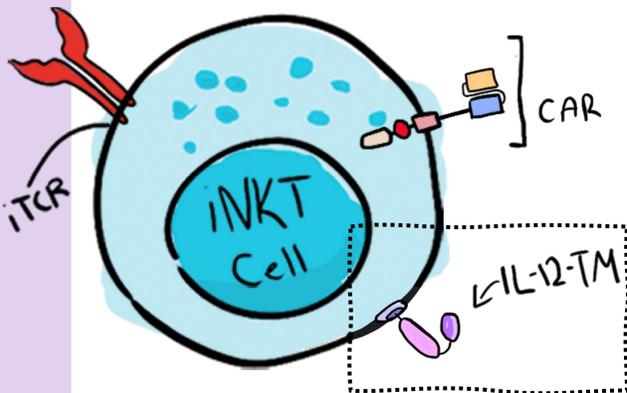
IL-12-TM is a modified version of IL-12

with a membrane anchor that links it to the surface of CAR-iNKT cells. We have designed it to be attached to the surface of iNKT cells so that 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

Discover how our IL-12-TM cytokine technology works in our new [IL-12-TM explainer whiteboard video](#).



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 antitumour activity

compared to CAR-iNKT cells lacking the cytokine

Arovella has entered into a **Sponsored Research Agreement** with Prof. Dotti’s group at the University of North Carolina

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

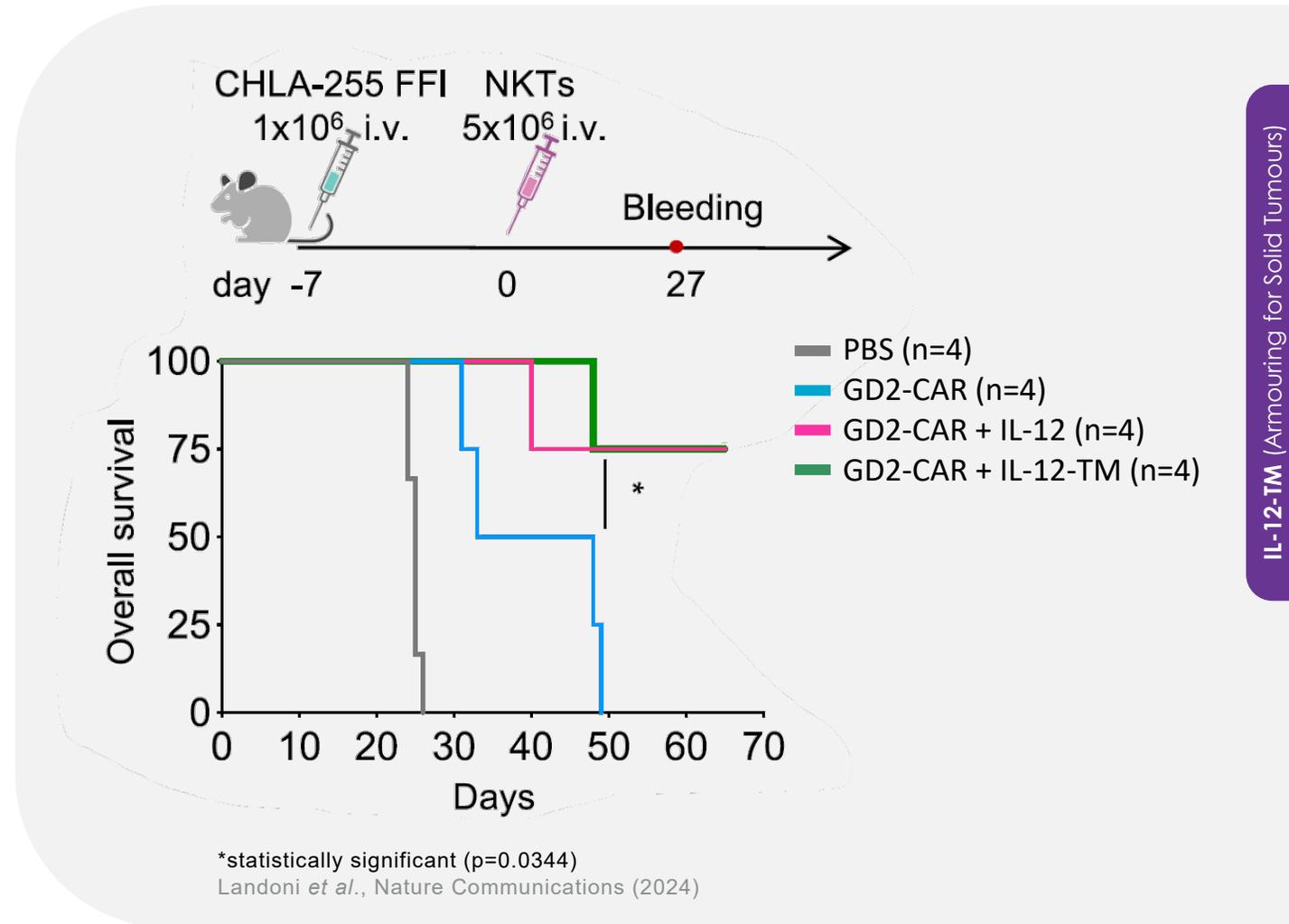
Article | [Open access](#) | [Published: 02 January 2024](#)

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

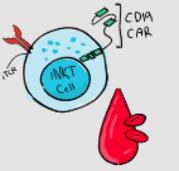
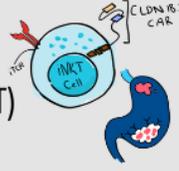
IL-12-TM enhances antitumor activity of CAR-iNKT cells

- Tumour cells positive for 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 + IL-12 or IL-12-TM remained alive
- IL-12-TM enhances CAR-iNKT cell numbers and antitumour activity



Arovella's expanding pipeline



PRODUCT	INDICATION	PRECLINICAL	IND-ENABLING	PHASE 1
ALA-101 (CD19 CAR-iNKT) 	CD19-positive cancers	CD19-positive Lymphoma		
ALA-105 (CLDN18.2 CAR-iNKT) 	CLDN18.2-positive solid tumours	Gastric & Pancreatic Cancers		

Upcoming Milestones

ALA-101
 Commence phase 1 clinical trial for patients with CD19-positive lymphoma and leukaemia

ALA-105
 Generate preclinical data for the CLDN18.2 CAR in iNKT cells with the addition of IL-12-TM armour

Investment highlights

ALA-101 (CAR19-iNKT)

- Clinic ready, following U.S. FDA acceptance of the IND, validating preclinical and manufacturing data
- Phase 1 clinical trials, expected to commence in FY 2026 for CD19-positive lymphoma and leukaemia patients



ALA-105 (CLDN18.2 CAR-iNKT)

- Promising data generated for Arovella's CAR targeting CLDN18.2
- The CAR will be incorporated into iNKT cells and tested using in vitro and animal models



CAR-iNKT – new cancer targets

- Negotiating license agreement with Baylor College of Medicine for iNKT cell IP and new CARs targeting solid tumours
- Continuing to screen across the globe for novel IP to enhance the platform



Corporate highlights

- Strong balance sheet (\$19.4 million¹), funded to early safety and efficacy readouts for the ALA-101 clinical trial
- Uniquely positioned as one of few companies globally developing CAR-iNKT cells for cancer treatment



Strong Leadership Team

SENIOR MANAGEMENT TEAM



Dr Michael Baker
CEO & MANAGING DIRECTOR



Dr Nicole van der Weerden
CHIEF OPERATING OFFICER



Dr Robson Dossa
VP MANUFACTURING & QUALITY



Dr Michelle Ferguson
SENIOR DIRECTOR RESEARCH & DEVELOPMENT



Jacqueline Cumming
SENIOR DIRECTOR CLINICAL DEVELOPMENT

BOARD OF DIRECTORS



Dr Elizabeth Stoner
INTERIM CHAIR



Dr Michael Baker
CEO & MANAGING DIRECTOR



Dr Debora Barton
DIRECTOR



Mr Gary Phillips
DIRECTOR



Dr Andrew Nash
DIRECTOR

Financial overview

Financial Snapshot

ASX CODE	ALA
Market capitalisation ¹	\$104.58 million
Shares on issue	1,202.1 million
52-week low / high	\$0.068 / \$0.1950
Cash Balance (31 Dec, 2025)	\$19.4 million

Major Shareholders

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

1. As of 30 January 2025
2. As of 22 August 2025 - Appendix 4E and Annual Report
3. Formerly Merchant Funds Management
4. Holding includes associated entities and parties

ALA Price and Volume - 12 Months¹



Notes



ASX:ALA



Thank You

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CEO & Managing Director

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