



ASX:ALA

Capital Raise
Investor Presentation
7 June 2023

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Arovella Therapeutics Highlights



Off-the-Shelf iNKT Cell Platform

Arovella is developing off-the-shelf iNKT cell therapies to target blood cancers and solid tumour cancers



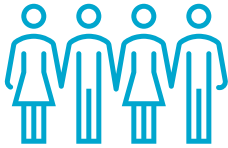
Lead Product Advancing to Clinic

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



Addressing Key Unmet Need

Arovella's iNKT cell platform is well positioned to solve key challenges that hamper the cell therapy sector



Strong Leadership Group

Arovella's leadership team and its Board have proven experience in drug development, particularly cell therapies



Strategic Acquisitions

Arovella is 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

Arovella Financial Overview

Financial Snapshot

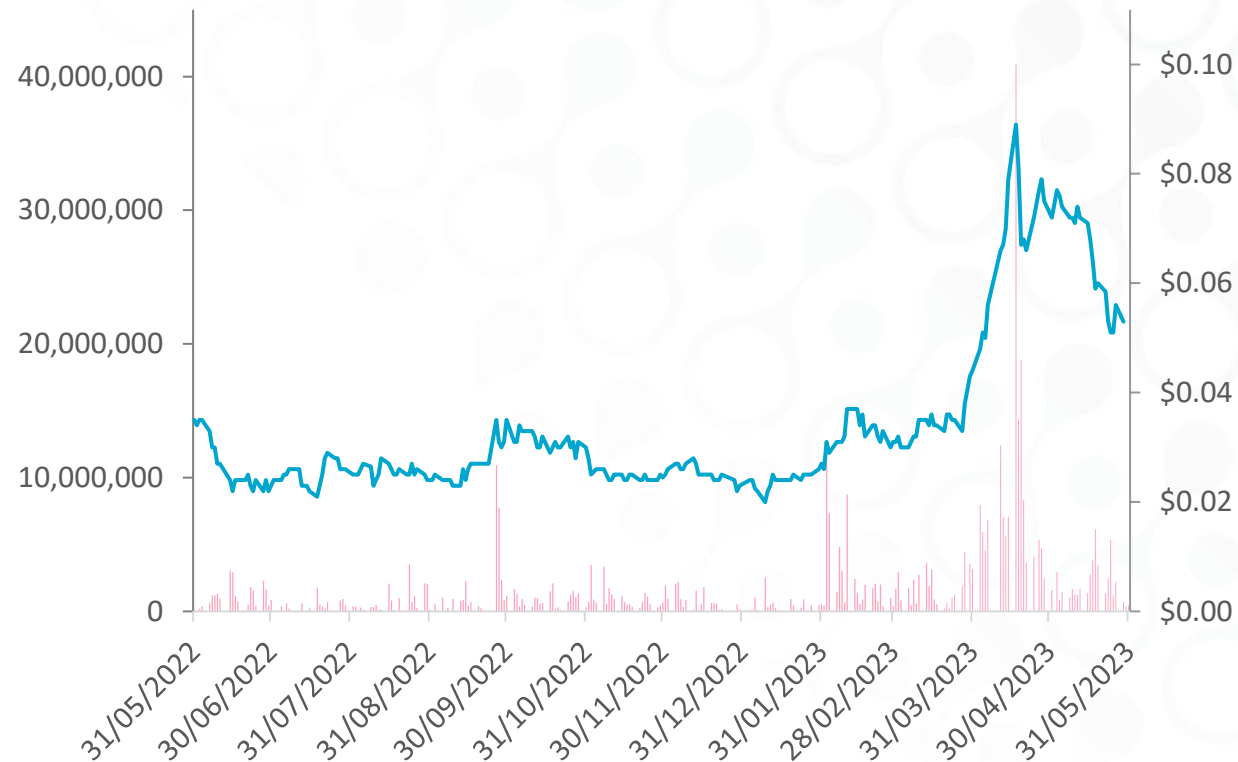
ASX CODE	ALA
Market capitalisation ¹	\$37.1 million
Shares on issue	758.8 million
52-week low / high	\$0.020 / \$0.105
Cash (31 March 2023)	\$3.2 million

Major Shareholders





















Shareholder	Ownership (%) ¹
THE TRUST COMPANY (AUSTRALIA) LTD	54,516,657 (7.28%)
MANN BEEF PTY LTD	20,000,000 (2.67%)
BLACKBURNE CAPITAL PTY LTD	17,800,000 (2.38%)
UBS NOMINEES PTY LTD	15,064,640 (2.01%)
DYLIDE PTY LTD	15,000,000 (2.00%)

1. As of 31 May 2023

ALA Price and Volume - 12 Months



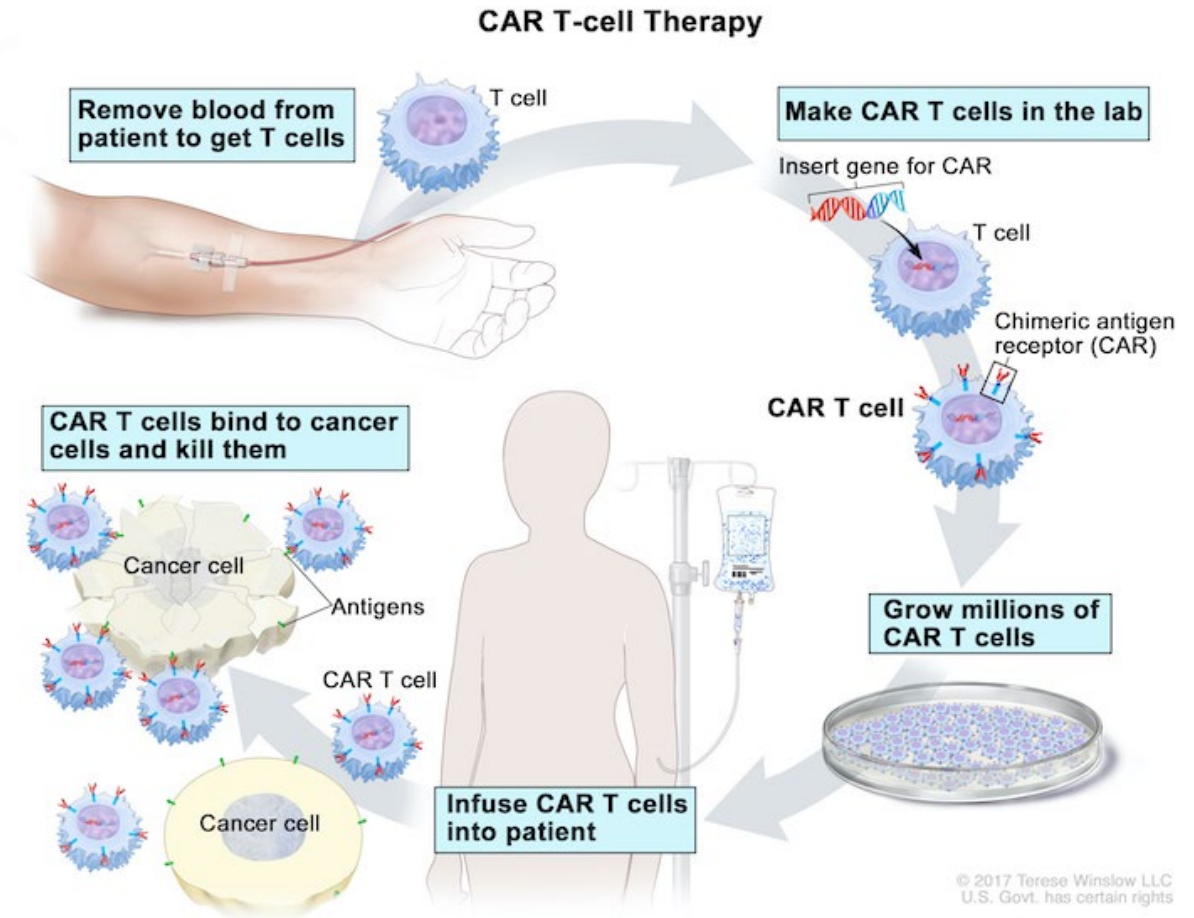
Recent Cell Therapy Transactions

Date	Type of deal	Acquirer/Licensee	Target/Licensors	Stage	Upfront (\$M)	Milestones (\$M)	Total deal value
May-23	License			Phase Ib	\$245	undisclosed	
Jan-23	Acquisition			Phase I	\$200	\$120	\$320
Oct-22	Development collaboration			Phase II	\$225*	undisclosed	
Sep-22	Research collaboration			Preclinical	\$70	undisclosed	
Aug-22	Licence and strategic collaboration			Phase I	\$110	\$110	\$220
Sep-21	Development collaboration			Preclinical	\$150	\$150	\$300
Aug-21	Research collaboration			Preclinical	undisclosed	undisclosed	\$875
May-21	Acquisition			Phase I	\$70	\$115	\$185
Jun-21	Acquisition			Preclinical	\$125	\$0	\$125
Dec-19	Acquisition			Preclinical	\$120	\$545	\$665
				Mean	\$146	\$208	\$364

*Arcellx also received a \$100m equity investment from Gilead

What are “CAR-T Cells”?

- T cells are a common type of immune cell that fight infections and can help fight cancer
- 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 is able to specifically recognise cancer cells through a target antigen
- 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>

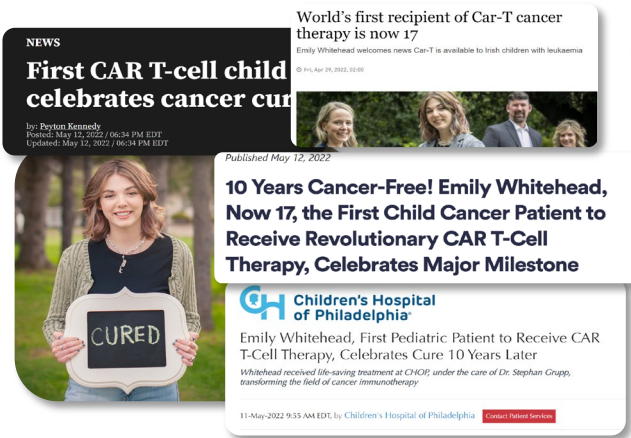
Cell Therapy Has Revolutionized Blood Cancer Treatment

- CAR-T cells have demonstrated ability to **cure** haematological cancers and have generated strong sales
- The Cell Therapy market is expected to reach \$12.3 billion by 2030¹

February 2022



May 2022



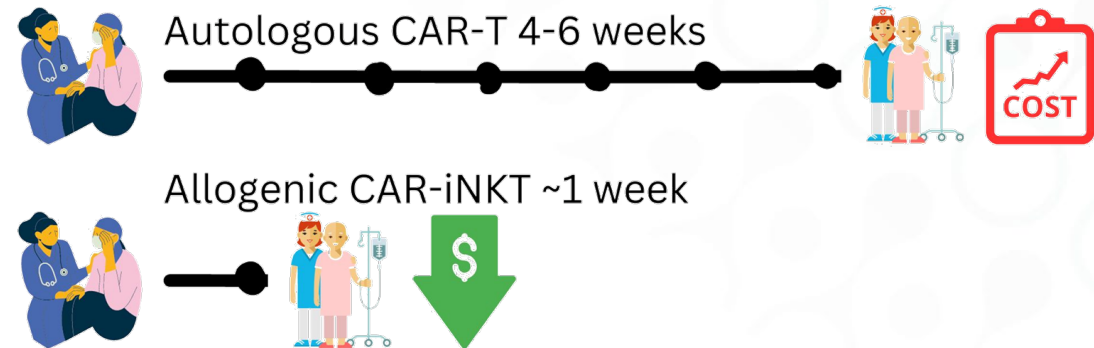
Product	Approval Year	2022 Revenue
 YESCARTA [®] (axicabtagene ciloleucel) Suspension for IV infusion	2017	US\$1160m ²
 KYMRIAHA [®] (tisagenlecleucel) Suspension for IV infusion	2017	US\$536m ³
 Abecma [®] (idecabtagene vicleucel) Suspension for IV infusion	2021	US\$388m ⁴

<https://www.businesswire.com/news/home/20221214005817/en/Global-Cell-Therapy-Technologies-Market-to-Reach-12.27-Billion-by-2030-at-a-14.5-CAGR---ResearchAndMarkets.com>
1. https://s29.q4cdn.com/585078350/files/doc_financials/2022/q4/GILD-Q4-FY22-Earnings-Press-Release-2-February-2023.pdf
2. <https://www.novartis.com/sites/novartis.com/files/q4-2022-media-release-en.pdf>
3. <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.>

But...Manufacturing and Logistics Pose Major Challenges

- **T cells must originate from the patient to be treated** so each manufacturing batch is patient-specific
 - **High manufacturing and supply chain costs** lead to high drug costs (>\$500k per patient)
 - Starting material (T cells) can be compromised due to disease, **reducing efficacy**
 - Limited number of centres able to collect cells and manufacture the therapy so **not all eligible patients can be treated**
- **Manufacturing CAR-T takes 4-6 weeks** for each patient
 - Patients with aggressive disease sometimes **die while waiting for treatment**
 - **Manufacturing run failures can occur**, further increasing the time to treatment (and cost)

Arovella's allogeneic CAR-iNKT cell platform has the potential to address the manufacturing and logistics challenges of CAR-T cells and the potential for improved efficacy



Advantages of iNKT Cells

Cells from a healthy donor can be used to treat patients (no GvHD)

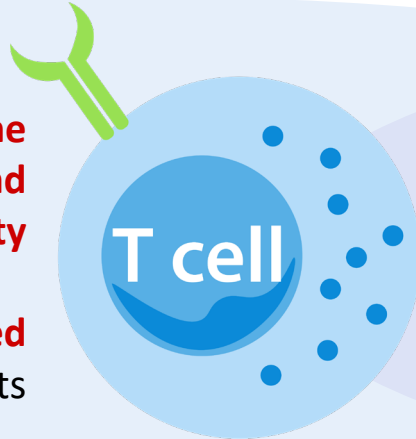
Naturally target tumour cells through invariant TCR (CD1d); **dual targeting with CAR**

Directly kill tumour cells via T-cell and NK-cell-like mechanisms

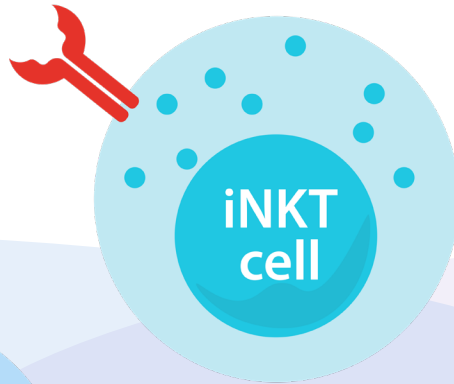
ADAPTIVE IMMUNITY

Can cause **severe cytokine release syndrome and neurotoxicity**

Complex gene editing required for allogeneic products



iNKT cells
subpopulation of T cells with properties of NK cells



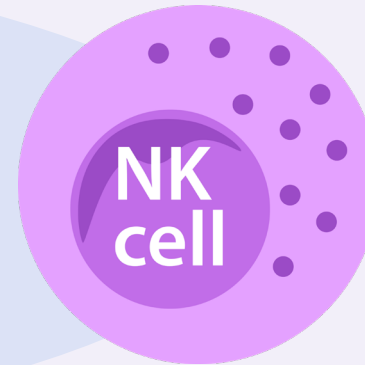
Modify the tumour microenvironment and **kill cells that promote tumour growth**

Infiltrate tumours and once activated, secrete signaling molecules to **activate other immune cells** to kill tumour cells

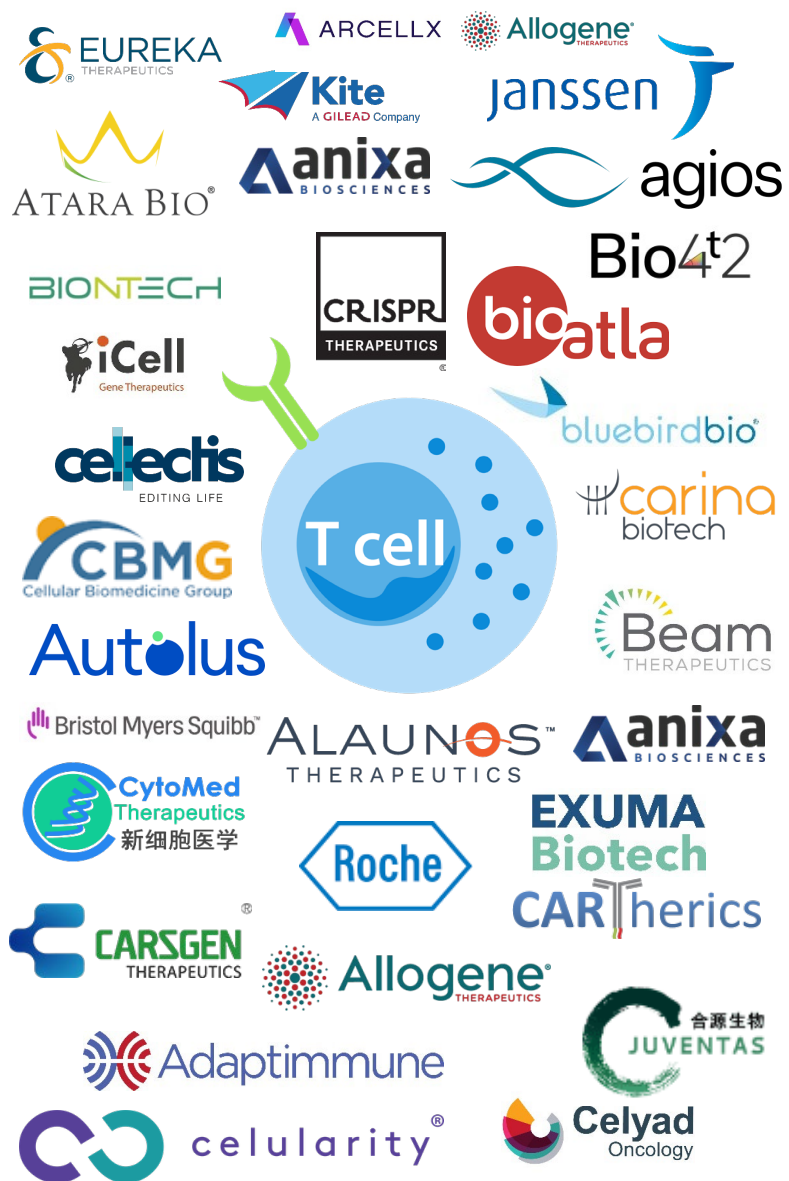
INNATE IMMUNITY

Limited persistence in an allogeneic setting

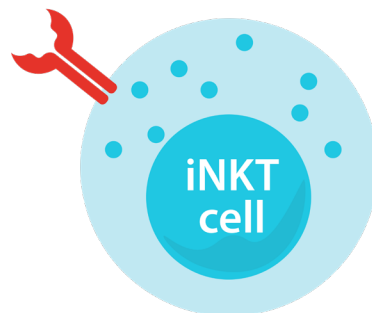
Limited durability of response



The Potential of CAR-iNKT Cells is Untapped



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

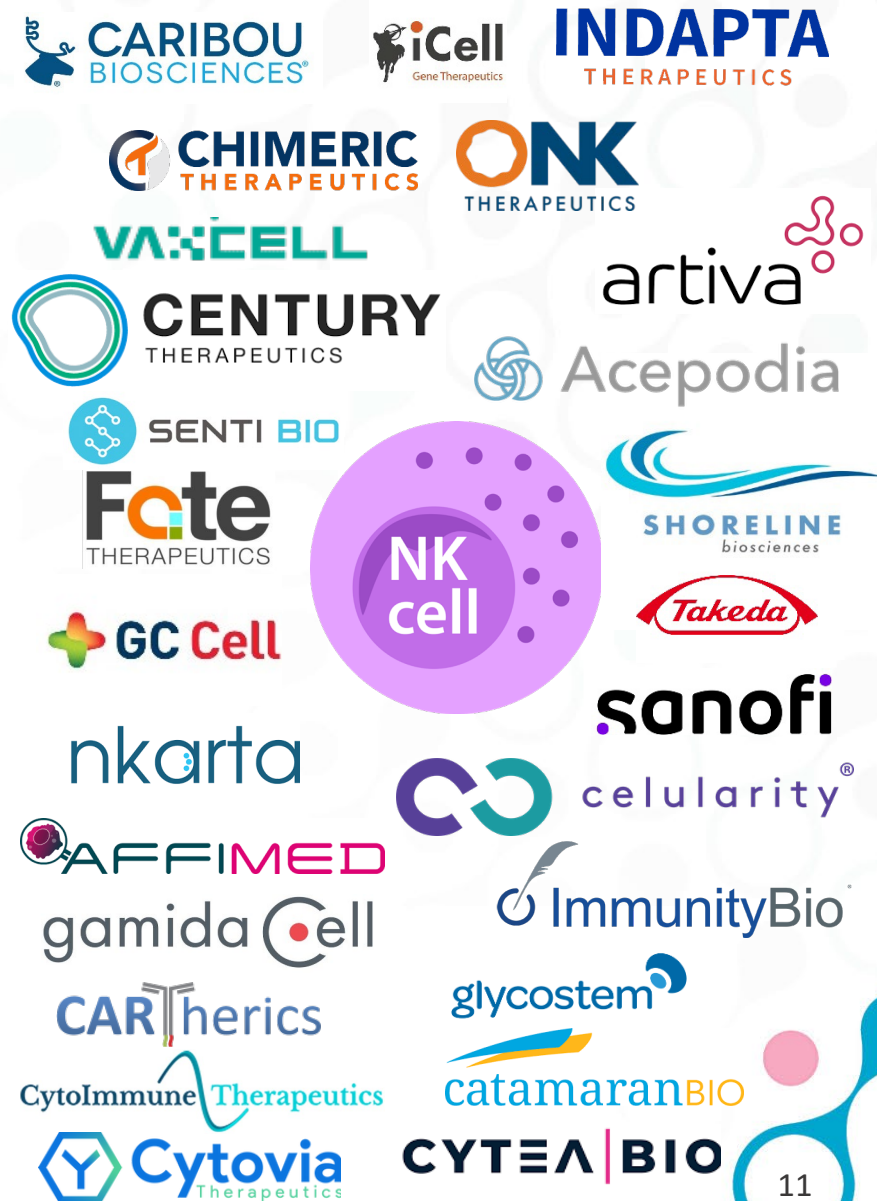


Athenex

Akesobio

MiNK
Therapeutics

APPIA BIO



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

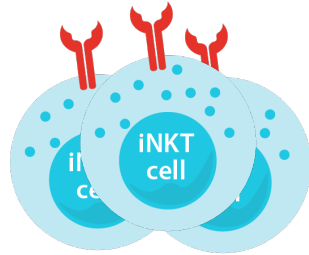
CAR-iNKT Cell Therapy Production Advantages

MANUFACTURING

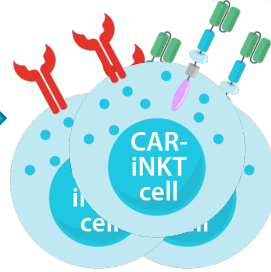
Collect Healthy Donor Blood



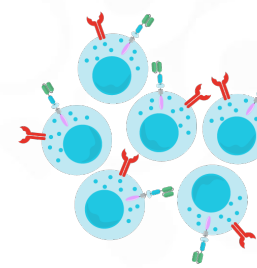
Isolate iNKT cells



Engineer iNKT cells to produce a CAR



Expand to grow billions of CAR-iNKT cells



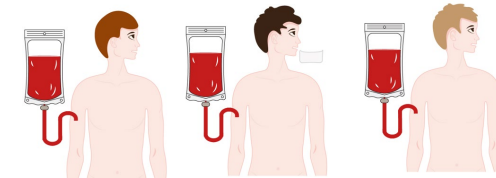
Vial and freeze CAR-iNKT cells



Thaw CAR-iNKT cells



Dose eligible patients

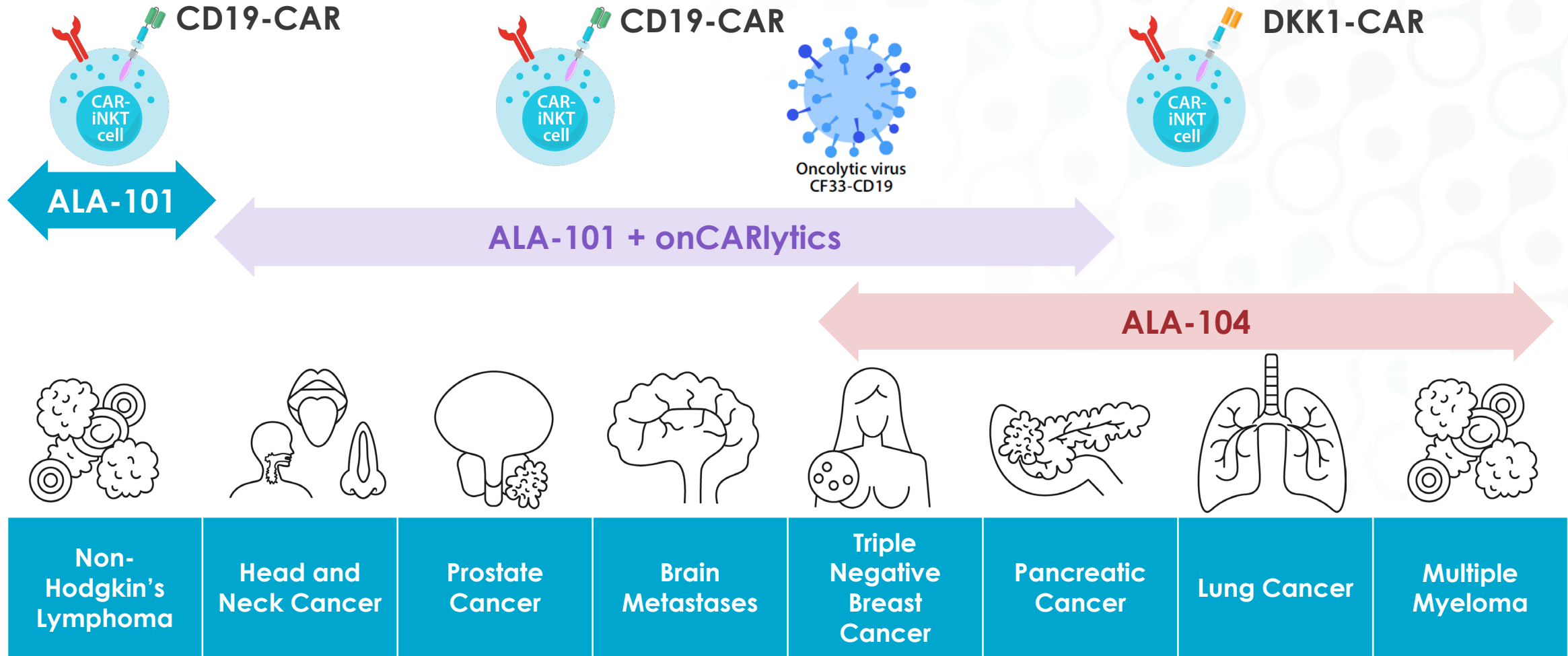


TREATMENT

Allogeneic Manufacturing Advantages

1. Healthier starting material
 - Potentially better efficacy
2. Scalable manufacturing with reduced costs
 - Reach more patients
3. Faster access to treatment
 - Improved outcomes for aggressive cancers
4. Removes risk of manufacturing run failure

Arovella's Potential Cancer Targets



- Additional CARs can be used to target different cancer types:

- Blood Cancers** - CD20, CD22, CD79b; **Solid tumours** – mesothelin, EGFRvIII, IL13 α 32, GPC3, HEPG2, GD2

CAR19-iNKT (**ALA-101**)

An off-the-shelf cell therapy for
CD19-expressing cancers



CD19-expressing Blood Cancers

Incidence



CD19 is commonly expressed on B cell blood cells, including:

B cell Non-Hodgkin's Lymphomas
Annual incidence of ~65,000 in the US¹ and ~95,000 in Europe²

More than 60% of patients do not achieve long-term remission with first-line approved therapies

B cell Leukaemias
Annual incidence of ~23,000 in the US (~5,500 deaths)¹

Current Treatments



Two approved autologous CAR T products target CD19

Autologous CAR-T recently elevated to 2nd-line therapy

6-month complete response rates for auto-CAR-T in relapsed and refractory DLBCL is only 30-35%

Substantial safety risk with high rates of CRS, ICANS and infection

Significant unmet need remains

ALA-101 solution



ALA-101 is an off-the-shelf iNKT cell therapy that targets CD19-expressing cancer cells

ALA-101 is an attractive potential treatment for B cell Lymphomas and Leukaemias

Phase I clinical trial in Non-Hodgkin's lymphoma expected to commence in 2024

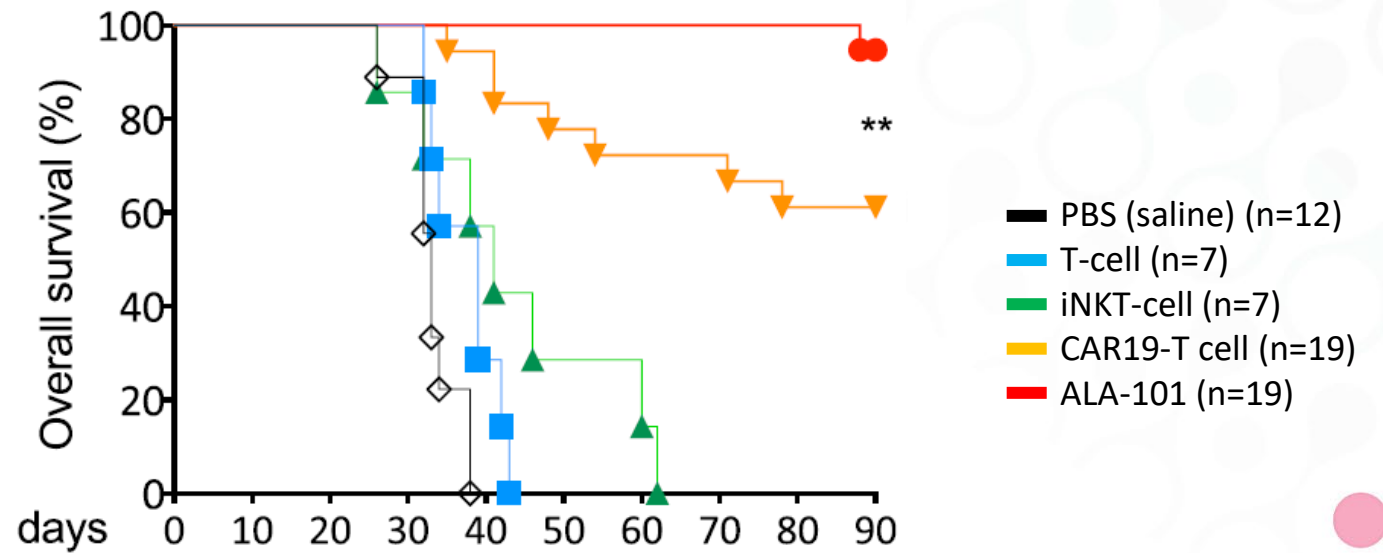
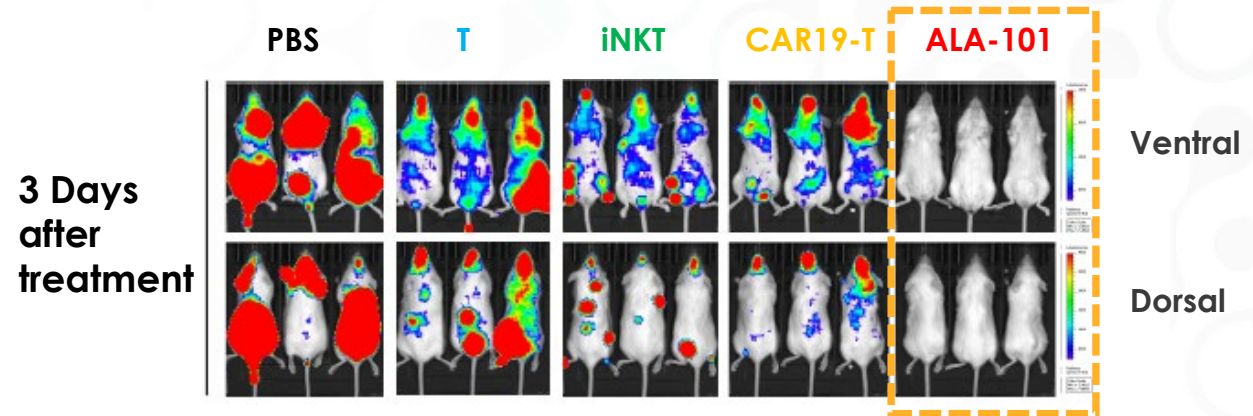
NHL = Non-Hodgkin's Lymphoma; DLBCL = Diffuse Large B Cell Lymphoma; CRS = Cytokine Release Syndrome; ICANS = Immune Effector Cell Associated Neurotoxicity Syndrome

1. American Cancer Society, Cancer Facts and Figures 2023, 2. IHE, Comparator Report on Cancer in Europe 2019, 3. <https://www.targetedonc.com/view/epidemiology-in-b-cell-malignancies>

ALA-101: Superior Activity Over CAR-T Cells

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

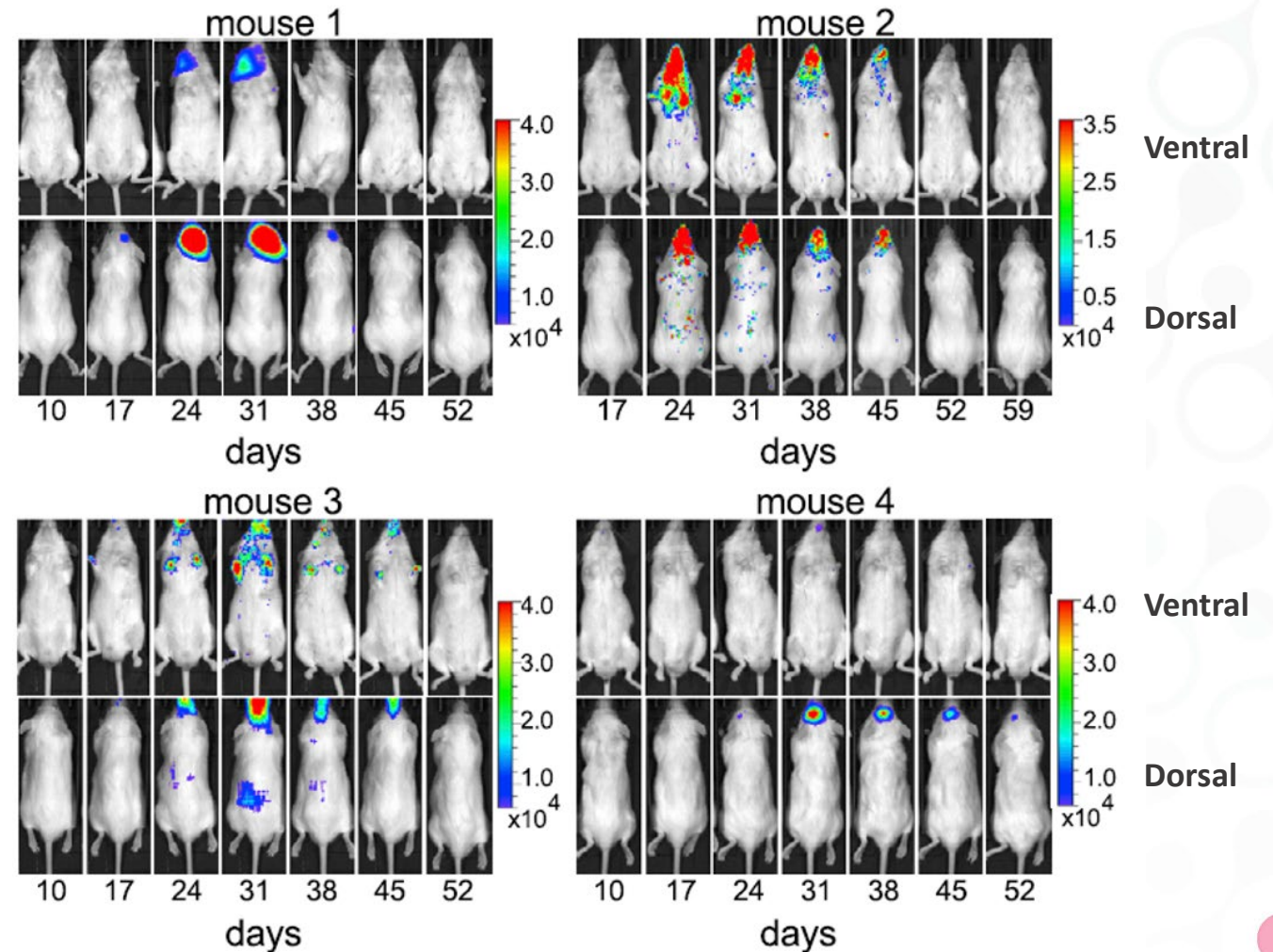
- Tumour cells expressing CD19 and CD1d were intravenously delivered into mice
- Mice were treated with:
 - PBS (saline)
 - Unmodified T cells (T)
 - Unmodified iNKT cells (iNKT)
 - CAR19-T cells
 - ALA-101
- After 90 days, only mice treated with CAR19-T cells or ALA-101 remained alive
- 1.5x more mice 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**



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)

New Data Presented at AACR 2023



Key Highlights:

- iNKT cells could be **well expanded**
- Following expansion, ALA-101 cells **retained the ability to multiply further when exposed to tumour cells** that express CD19
- Once stimulated, ALA-101 cells **express anti-cancer cytokines**
- ALA-101 **killed tumour cells that express CD19**, including primary patient tumour cells
- ALA-101 **significantly extended the lifespan of mice** with aggressive human B-Cell Acute Lymphoblastic Leukemia (B-ALL)

Summary



- Arovella's proprietary manufacturing process allows for efficient expansion of iNKT cells while retaining functionality
 - *Essential to produce multiple doses from a single batch and address the manufacturing costs and logistical challenges of current autologous therapies*



- Arovella has produced ALA-101 using a 3rd-generation lentiviral vector from Lentigen Technologies, Inc., in preparation for the manufacture of clinical material
 - *Lentiviral vector and genetic elements with proven safety profile*



- ALA-101 conferred significant anti-tumour effect and significantly extended lifespan in an aggressive model of human B-Cell Acute Lymphoblastic Leukemia (B-ALL)
 - *Confirming the potential of ALA-101 as an effective treatment for CD19+ leukemias and lymphomas*

Arovella continues to progress ALA-101 towards first-in-human clinical trials



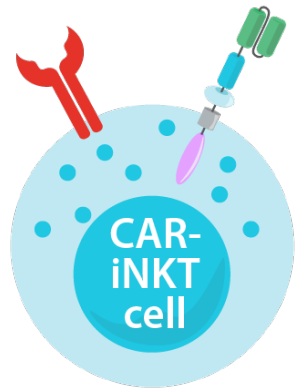
ALA-101 + CF33-CD19

An off-the-shelf cell therapy and
oncolytic virus combination to
mark and destroy solid tumours



Combining ALA-101 and CF33-CD19 (onCARlytics)

- ALA-101 is very potent and is rapidly activated to kill CD19 expressing cancers¹
- The product is being developed as an off-the-shelf product for cancer treatment

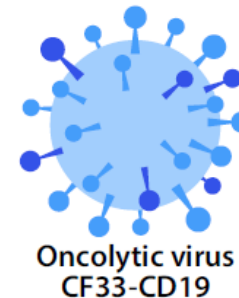


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THERAPEUTICS
**Imperial College
London**

1. <https://pubmed.ncbi.nlm.nih.gov/30300581/>
2. <https://pubmed.ncbi.nlm.nih.gov/32032721/>
3. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9126033/>

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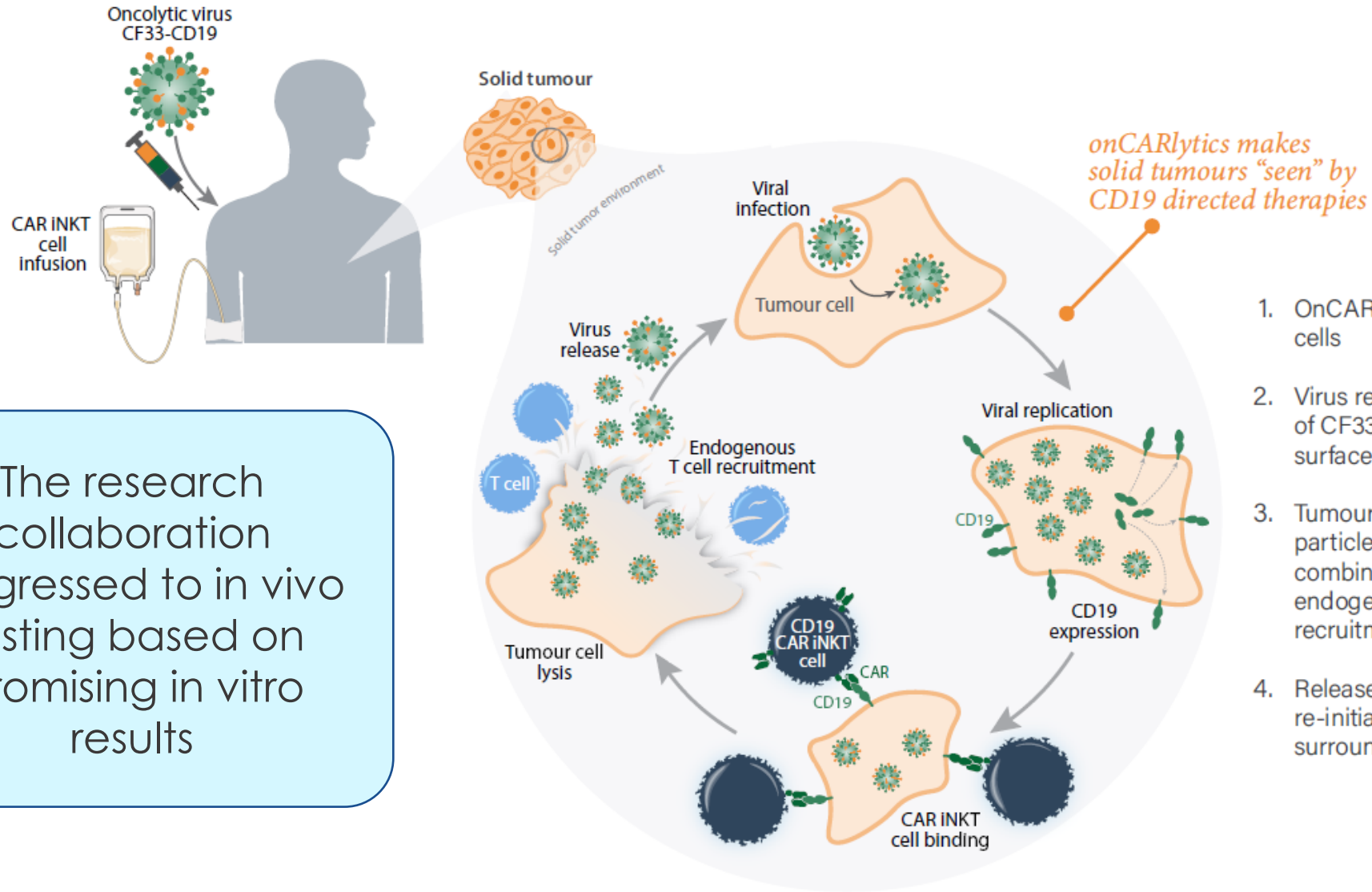
- CF33 is an oncolytic virus that targets tumour cells²
- CF33 has been engineered to induce CD19 expression after tumour cells have been infected – onCARlytics³
- Phase 1 trials for CF33 commenced October 2021 with CHECKvacc and May 2022 with VAXINIA



 **IMUGENE**
Developing Cancer Immunotherapies

 **City of
Hope**

ALA-101 + onCARlytics Mechanism of Action



The research collaboration progressed to in vivo testing based on promising in vitro results

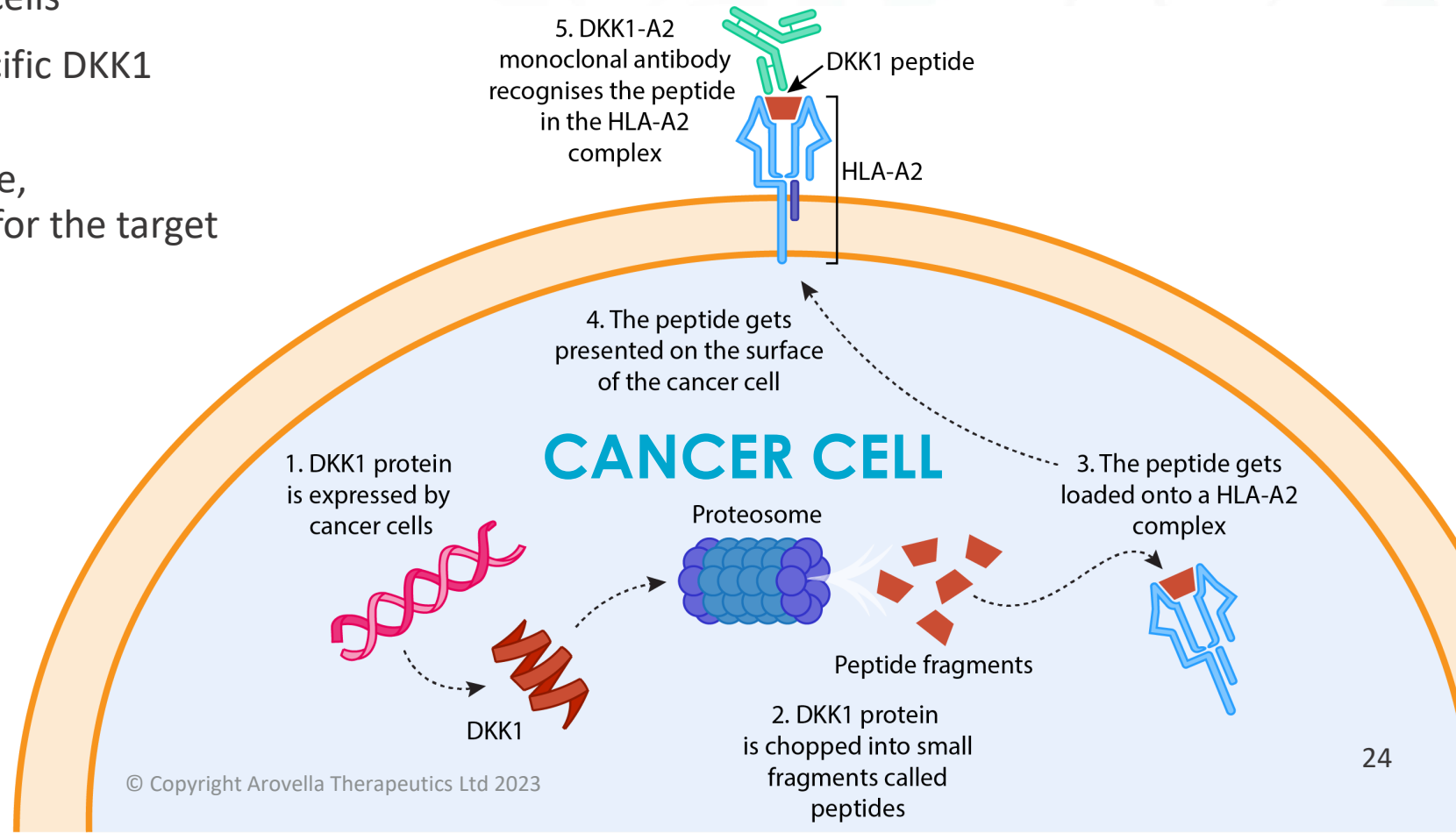
DKK1-CAR-iNKT Cells (**ALA-104**)

An off-the-shelf cell therapy for
multiple myeloma and potentially
solid tumours



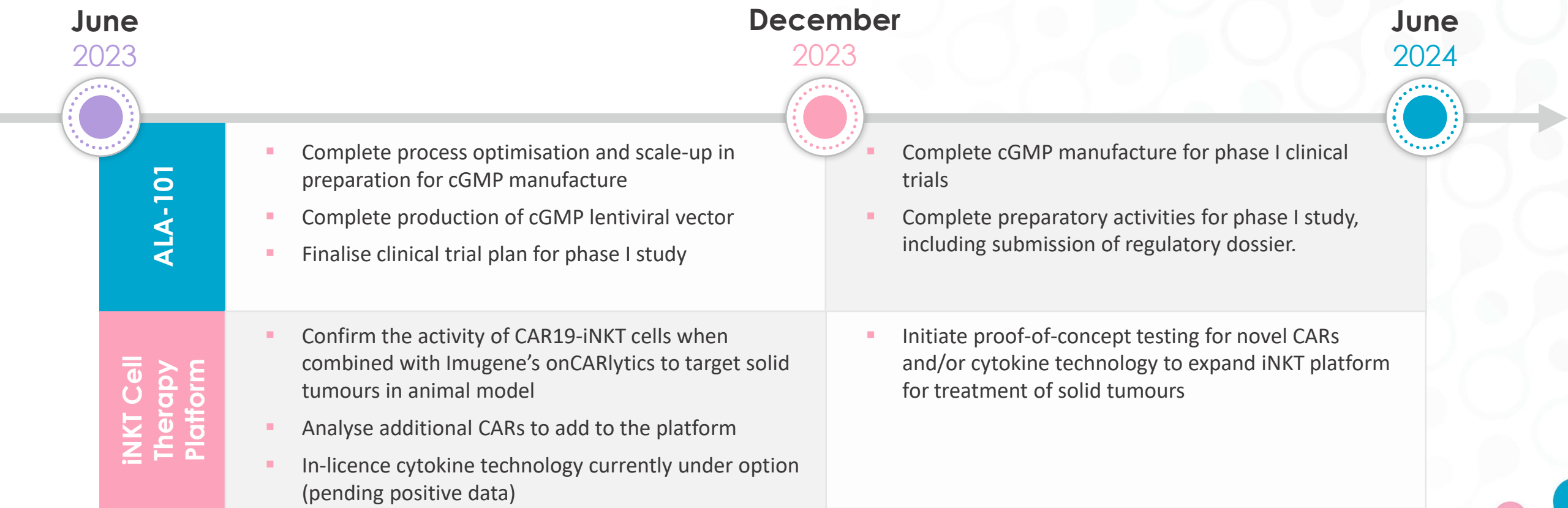
DKK1 is a Novel Cancer Target

- DKK1 is a secreted protein that functions as a negative regulator of the WNT signaling pathway
- DKK1 is overexpressed in numerous cancer types and DKK1 peptides are loaded onto immune complexes and presented at the surface of cancer cells
- Arovella's DKK1 mAb/CAR targets a specific DKK1 peptide in an HLA-A2 complex
- ~40-50% of the population is HLA-A2 +ve, representing a potentially large market for the target



Milestones FY2024

- Arovella expects to advance ALA-101 into a phase I first-in-human clinical trial during 2024
- Arovella also continues to assess novel complimentary technologies to expand the use of the iNKT platform to treat solid tumours



Arovella Has a Strong Leadership Team

LEADERSHIP



Dr. Michael Baker
CEO & MANAGING DIRECTOR



Dr. Nicole van der Weerden
CHIEF OPERATING OFFICER



Dr. Mini Bharathan
SENIOR VP DEVELOPMENT &
TRANSLATIONAL MEDICINE



Dr. Robson Dossa
SENIOR DIRECTOR
MANUFACTURING & QUALITY



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DIRECTOR



Mr. David Simmonds
DIRECTOR



Summary – Arovella's CAR-iNKT Cell Platform



A 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 I clinical trials, expected to commence in 2024



CAR-iNKT cells have multiple anticancer properties

CAR-iNKT cells are dual-targeting with enhanced cancer killing ability



Arovella has an expanding pipeline

Arovella continues to enter collaborations and licence agreements to expand use of the iNKT platform to treat solid tumours



Improved manufacturing logistics

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



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

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:

Dependency upon licence agreements

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.

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.

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.

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.

Key Risks

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.

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.

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.

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).

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.

General economic conditions

Arovella's operating and financial performance is influenced by a variety of general economic and business conditions such as to interest rates, exchange rates, inflation, government policy, taxation law, investor sentiment towards particular market sectors, demand for and supply of capital, national and international economic conditions (including any trade conflicts between major countries, terrorism, war, social upheaval or other hostilities) amongst others are outside the Company's control.

Key Risks

Litigation risk

In the ordinary course of business, Arovella may be involved in litigation disputes from time to time. These disputes could be brought by third parties including customers, suppliers, business partners and employees, and may adversely impact the financial performance and industry standing of Arovella.

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.

COVID19 Pandemic risk

The outbreak of the coronavirus disease (COVID-19) has had a material effect on global economic markets. The global economic outlook may face uncertainty due COVID-19 and similar virus outbreaks, which may have a significant impact on capital markets. Government measures to limit such viruses may adversely affect the Company.

International Offer Restrictions

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International Offer Restrictions

No action has been taken to register the securities or otherwise permit a public offering of securities in any jurisdiction. The distribution of this document outside Australia may be restricted by law. Persons who come into possession of this document should observe any such restrictions. Any failure to comply with such restrictions may constitute a violation of applicable securities laws. This document is not a prospectus and shall not constitute, or form part of, an offer to sell or a solicitation of an offer to buy securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities law of any such jurisdiction. In particular, this document may not be distributed to any person, and the New Shares may not be offered or sold, in any country outside Australia except to the extent permitted below.

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This document has not been registered, filed with or approved by any New Zealand regulatory authority under the Financial Markets Conduct Act 2013 (New Zealand) (the "FMC Act"). The New Shares are not being offered or sold in New Zealand (or allotted with a view to being offered for sale in New Zealand) other than to a person who:

- is an investment business within the meaning of clause 37 of Schedule 1 of the FMC Act;
- meets the investment activity criteria specified in clause 38 of Schedule 1 of the FMC Act;
- is large within the meaning of clause 39 of Schedule 1 of the FMC Act;
- is a government agency within the meaning of clause 40 of Schedule 1 of the FMC Act; or
- is an eligible investor within the meaning of clause 41 of Schedule 1 of the FMC Act.

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This document has not been, and will not be, registered as a prospectus under the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong, nor has it been authorised by the Securities and Futures Commission in Hong Kong pursuant to the Securities and Futures Ordinance (Cap. 571) of the Laws of Hong Kong (the "SFO"). No action has been taken in Hong Kong to authorise or register this document or to permit the distribution of this document or any documents issued in connection with it. Accordingly, the New Shares have not been and will not be offered or sold in Hong Kong other than to "professional investors" (as defined in the SFO and any rules made under that ordinance).

No advertisement, invitation or document relating to the New Shares has been or will be issued, or has been or will be in the possession of any person for the purpose of issue, in Hong Kong or elsewhere that is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to New Shares that are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors. No person allotted New Shares may sell, or offer to sell, such securities in circumstances that amount to an offer to the public in Hong Kong within six months following the date of issue of such securities. The contents of this document have not been reviewed by any Hong Kong regulatory authority. You are advised to exercise caution in relation to the offer. If you are in doubt about any contents of this document, you should obtain independent professional advice.

International Offer Restrictions

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Singapore

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This document has been given to you on the basis that you are (i) an existing holder of the Company's shares, (ii) an "institutional investor" (as defined in the SFA) or (iii) an "accredited investor" (as defined in the SFA). In the event that you are not an investor falling within any of the categories set out above, please return this document immediately. You may not forward or circulate this document to any other person in Singapore. Any offer is not made to you with a view to the New Shares being subsequently offered for sale to any other party. There are on-sale restrictions in Singapore that may be applicable to investors who acquire New Shares. As such, investors are advised to acquaint themselves with the SFA provisions relating to resale restrictions in Singapore and comply accordingly.

Thank You

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CEO & Managing Director

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Appendix

Dr. Michael Baker
CEO & Managing Director

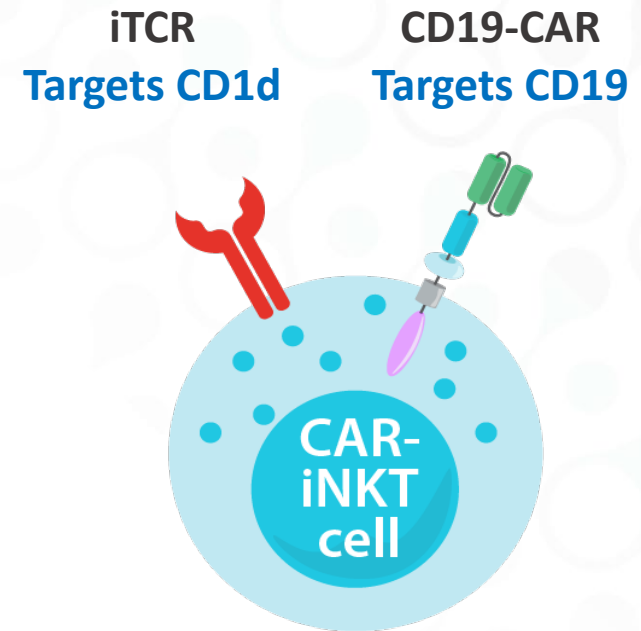
Email: investor@arovella.com

Mobile: +61 403 468 187



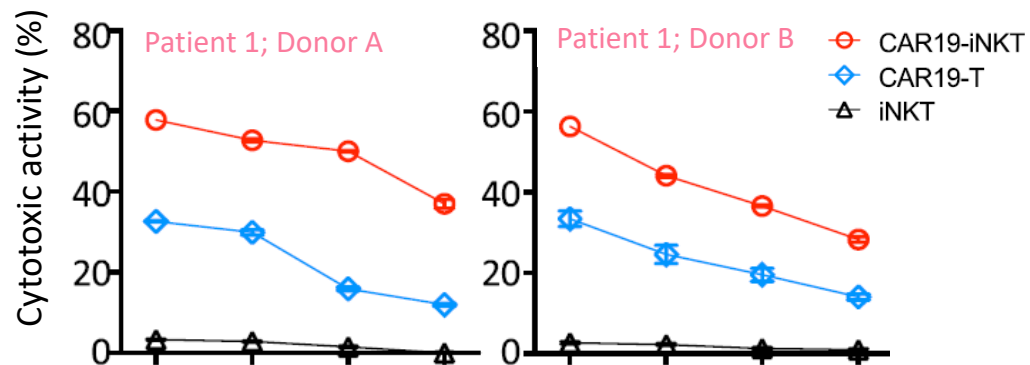
Development of ALA-101 (CAR19-iNKT Cells)

- Arovella's lead product is ALA-101, a CD19-targeting CAR-iNKT cell therapy
- The lentivirus for ALA-101 is manufactured using a third-generation lentiviral vector system
- ALA-101 is being developed for the treatment of malignant B-cell leukemias and lymphomas
 - CD19-targeting CAR T-cells is a proven therapeutic approach for treating lymphoma or B-cell leukemias

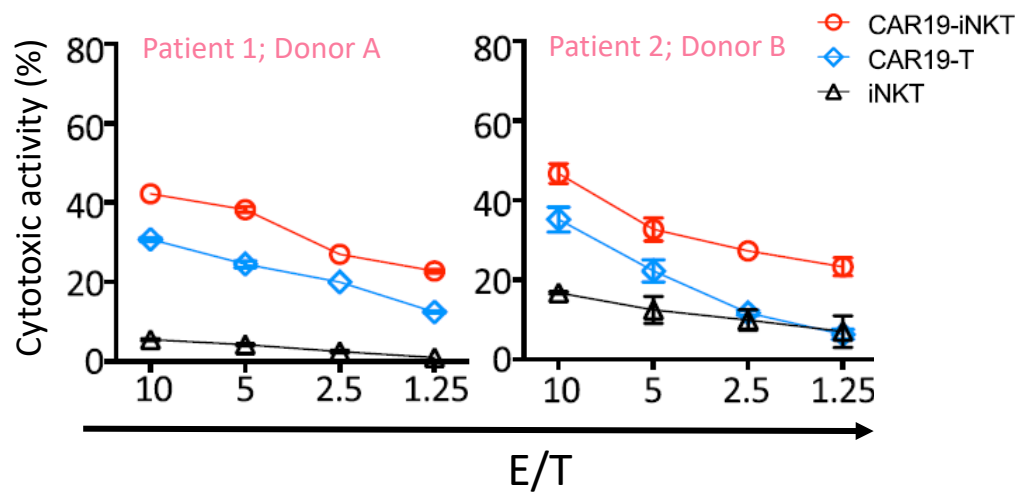


CAR19-iNKT Cells Enhanced Primary Tumor Cell Killing

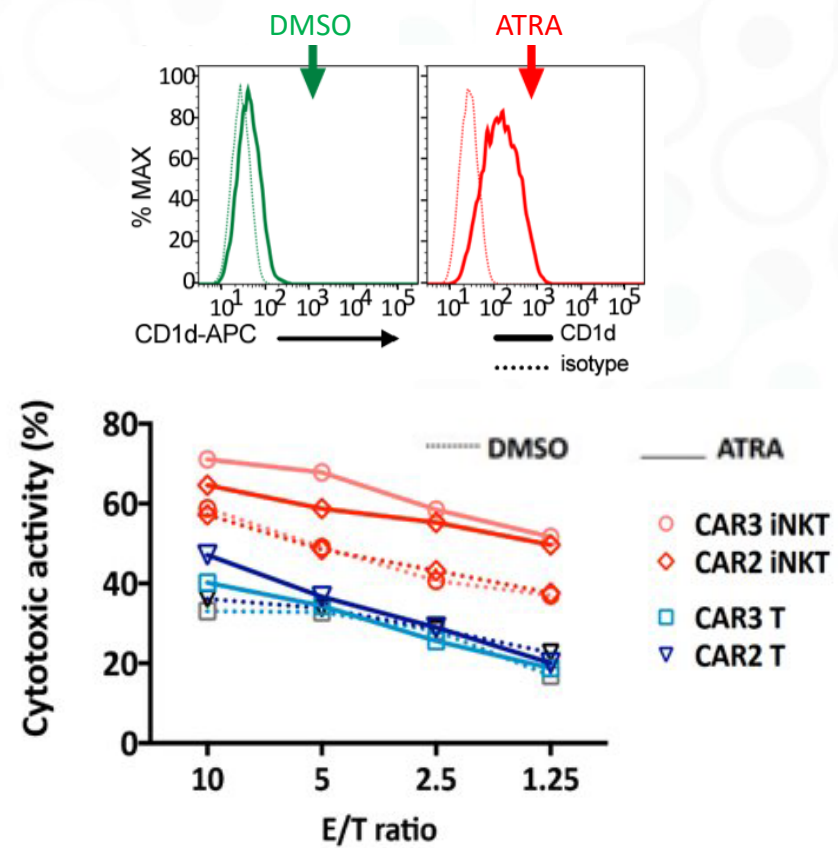
A. Mantle Cell Lymphoma



B. Marginal Zone Lymphoma



C. Chronic Lymphocytic Leukemia



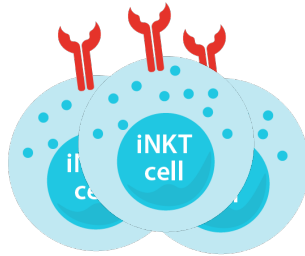
DMSO – dimethyl sulfoxide; ATRA – all-trans retinoic acid

CAR19-iNKT (ALA-101) Cells Can Be Expanded

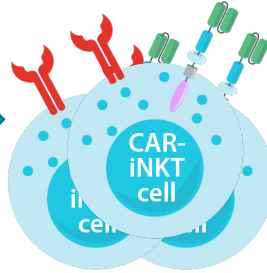
Collect Healthy Donor Blood



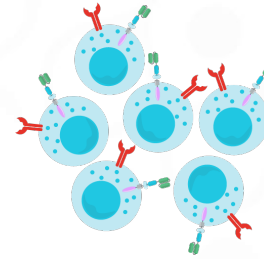
Isolate iNKT cells



Engineer iNKT cells to produce a CAR



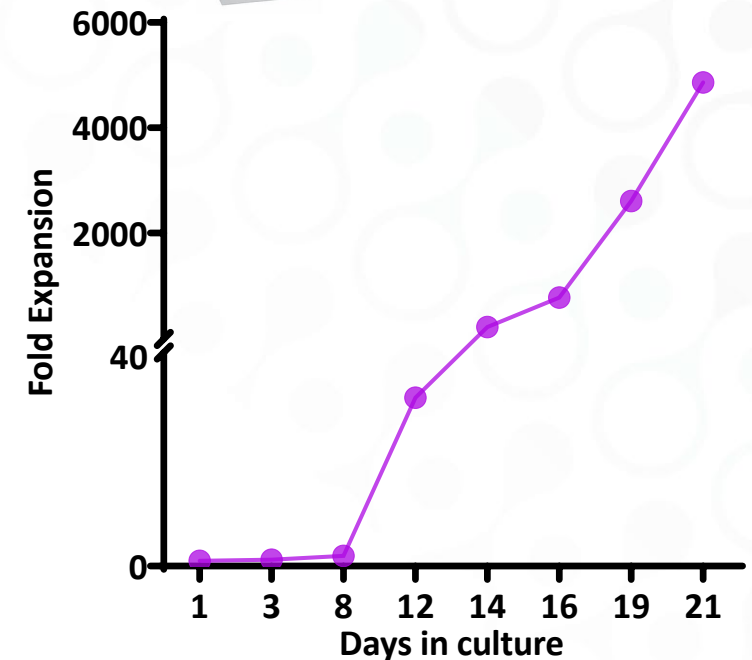
Expand to grow billions of CAR-iNKT cells



Vial and freeze CAR-iNKT cells



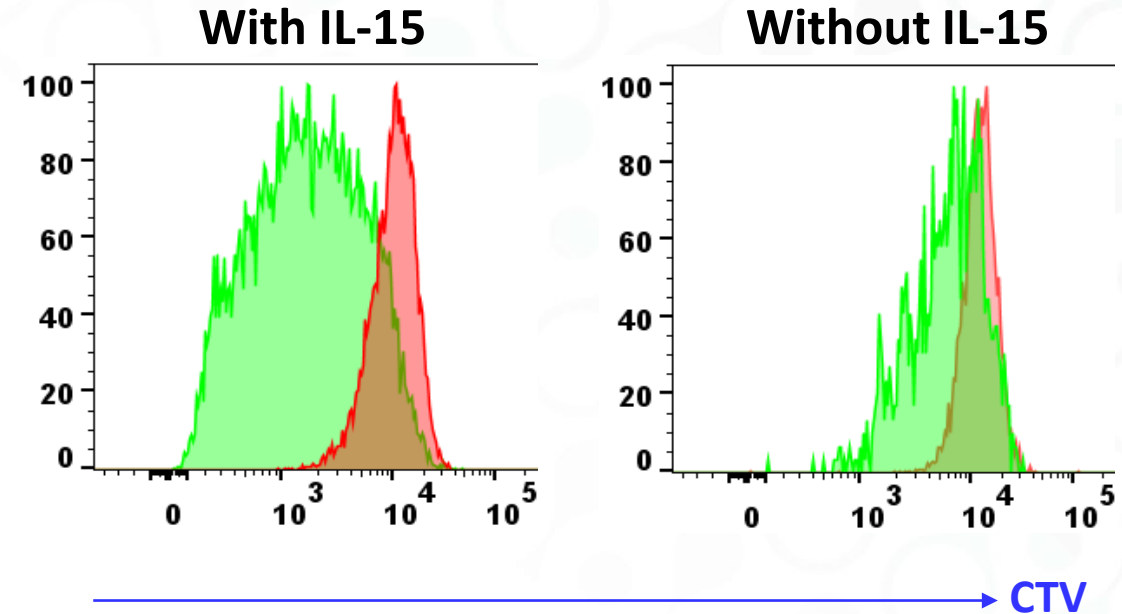
- iNKT cells from a healthy donor were modified to produce a CD19-targeting CAR using a 3rd generation lentiviral vector from Lentigen Technologies, Inc.
- Cells could be 'expanded' (multiplied) ~5,000-fold to produce large numbers of cells from a single batch
 - Expansion is key to producing an off-the-shelf therapy that addresses the logistical challenges of current autologous cell therapies and provides higher commercial returns through lower manufacturing costs



AACR Poster Fig 2(D)

Expanded iNKT Cells Retain the Ability to Proliferate

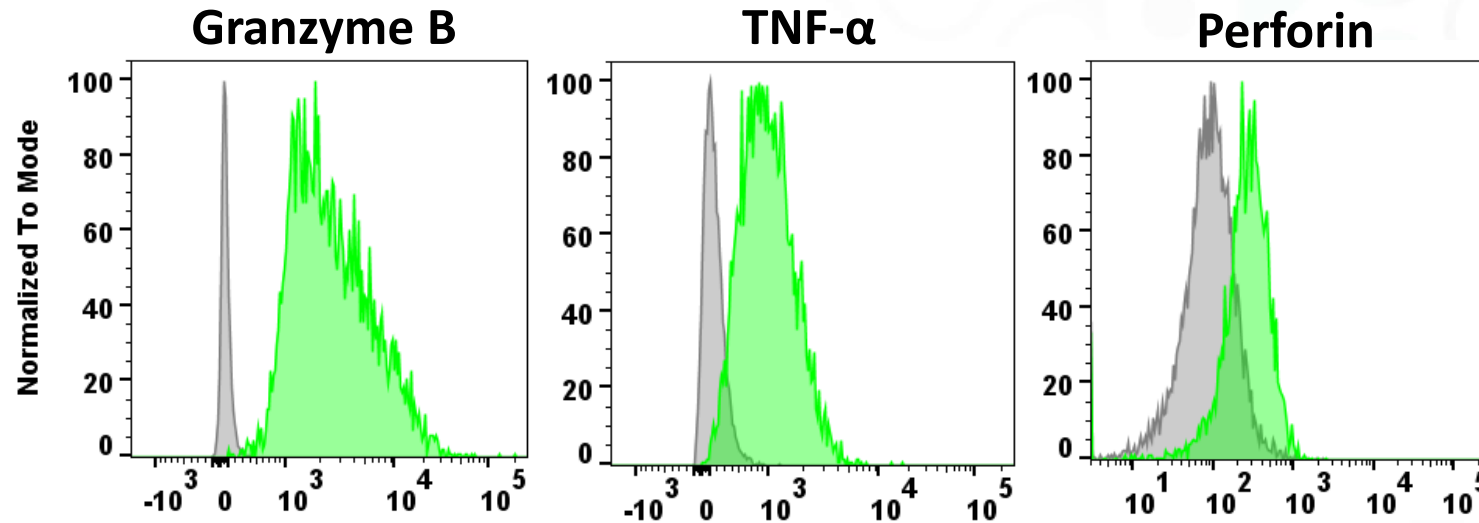
- ALA-101 cells that had been expanded ~5,000 fold were labeled with a fluorescent dye (CTV)
- Cells were then exposed to SEM tumour cells that were either **positive (CD19+)** or **negative (CD19-)** for CD19 expression on their surface
- Upon exposure to **CD19+** tumour cells, ALA-101 cells continued to divide and multiply
 - Cell division produces a shift in the signal to the left as a result of decreased CTV levels in the cells
- **This continued expansion is expected to occur in treated patients, enhancing persistence and efficacy**



AACR Poster Fig 4(B)

ALA-101 Releases Anti-Tumour Cytokines

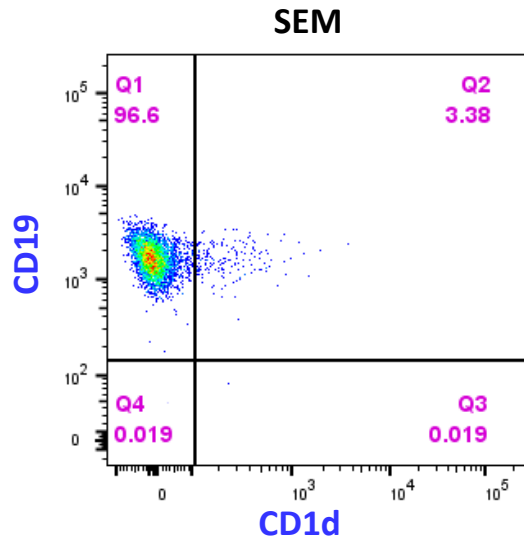
- When stimulated by tumour cells expressing CD19, ALA-101 cells dramatically up-regulated the anti-tumour cytokines Granzyme B, TNF- α and Perforin



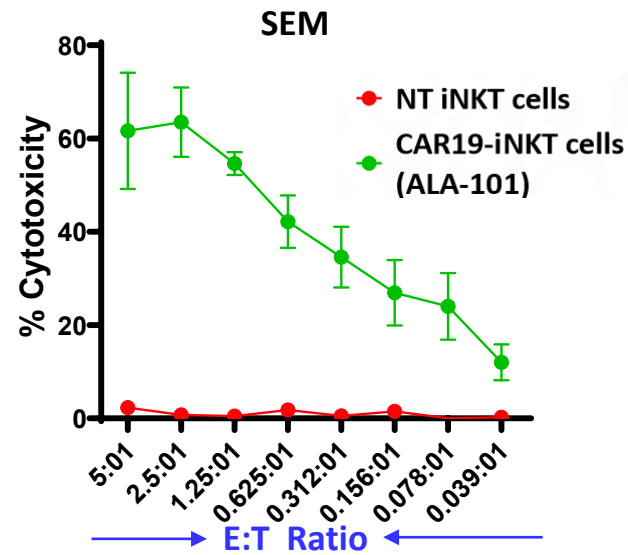
AACR Poster Fig 4(A)

ALA-101 Kills Tumour Cells That Express CD19

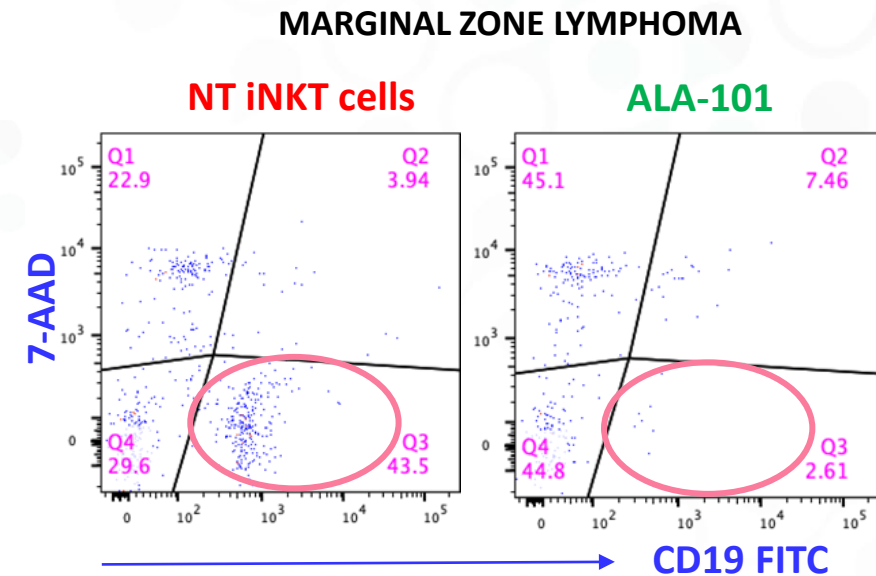
- SEM cells originate from a patient with an aggressive form of B-cell Acute Lymphoblastic Leukemia and express CD19, but not CD1d
- ALA-101 cells efficiently kill multiple leukemia cells lines, including SEM
- ALA-101 eradicated >90% of viable CD19+ cells from a marginal-zone lymphoma patient sample



AACR Poster Fig 3(A)



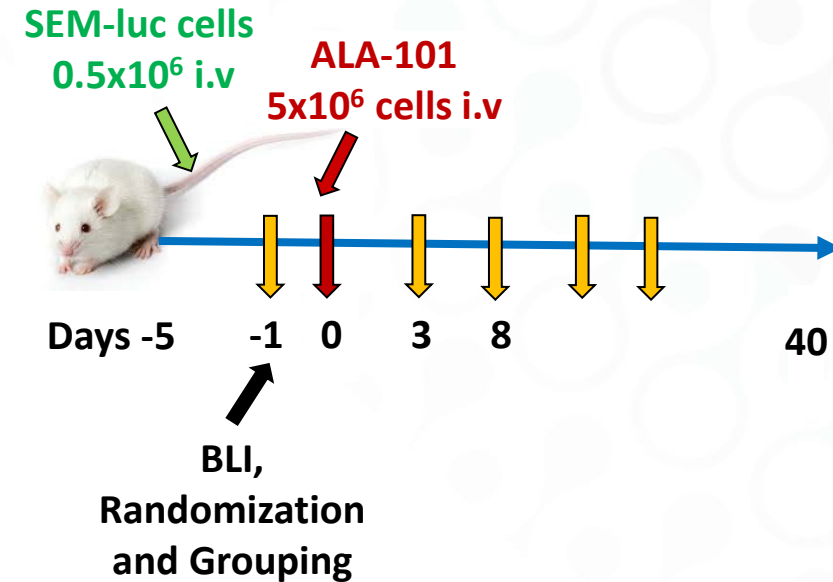
AACR Poster Fig 3(C)



AACR Poster Fig 3(B)

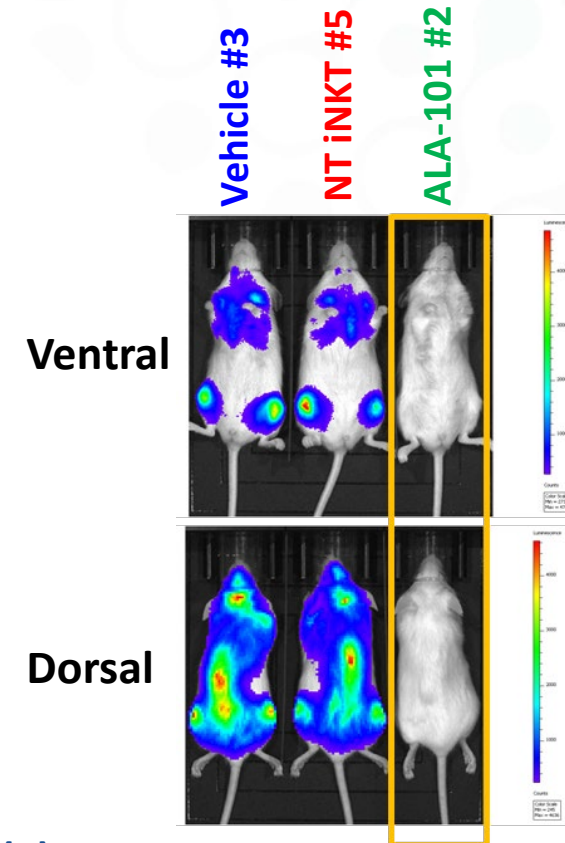
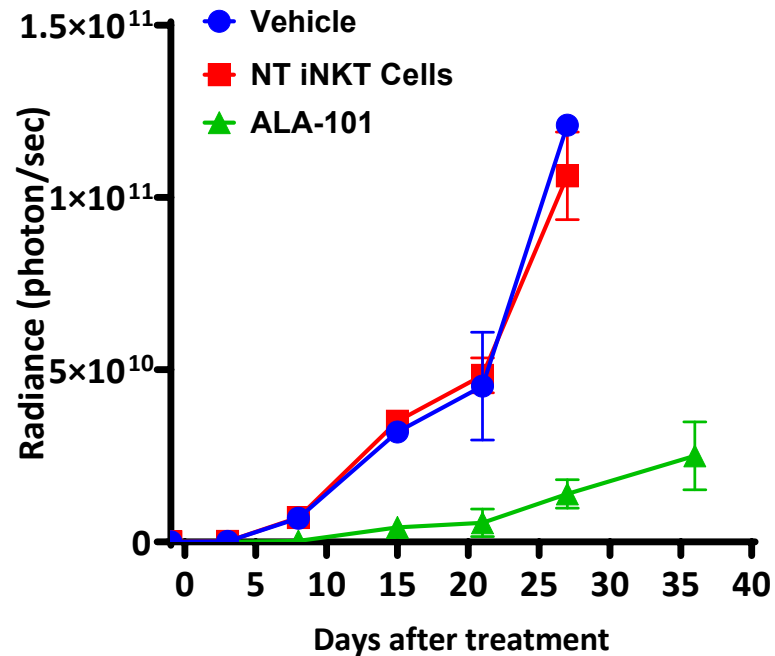
ALA-101 is Effective in an Aggressive Leukemia Model

- ALA-101 was tested in mouse model of B-Cell Acute Lymphoblastic Leukemia (B-ALL) model
- Mice were transplanted with SEM cells originating from a patient with an aggressive form of B-ALL
- After the tumour was established, mice were treated with a relatively low dose of ALA-101



ALA-101 Dramatically Reduced Tumour Burden

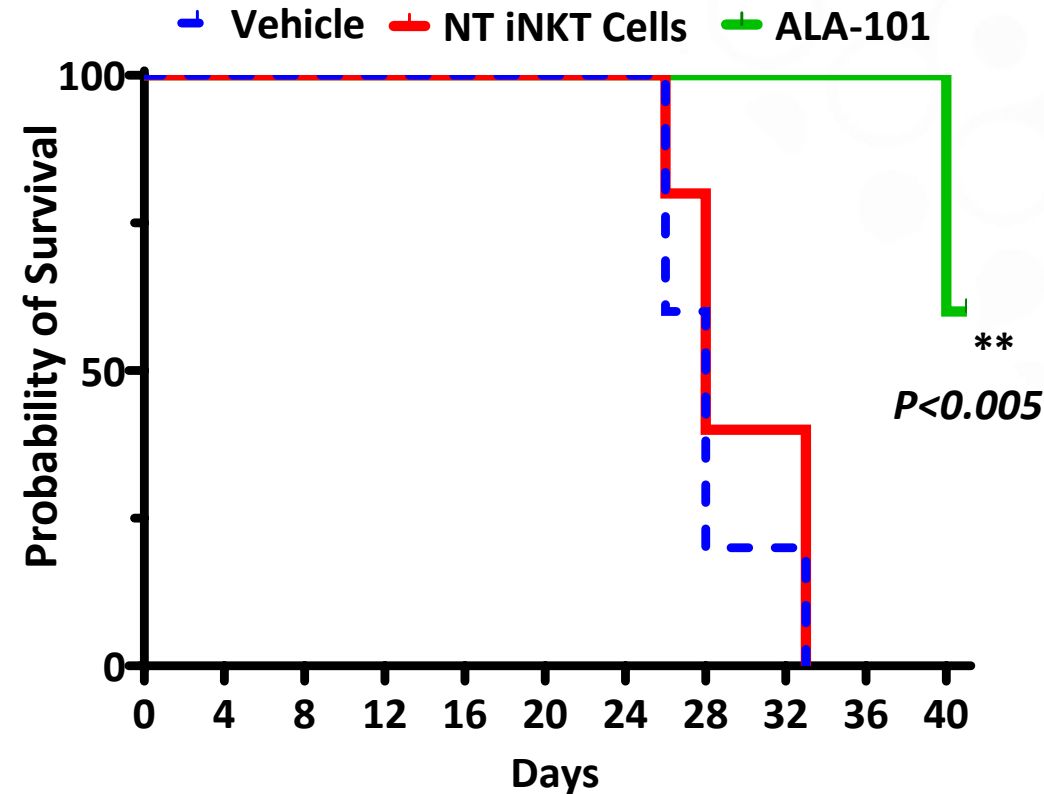
- After 26 days, tumour burden in ALA-101-treated mice was ~90% lower than control animals
- Bioluminescent imaging reveals substantially lower tumour burden in ALA-101-treated animals on Day 8



AACR Poster Fig 5(B) & (E)

ALA-101 Significantly Increased Animal Survival

- ALA-101 significantly enhanced the survival of the mice over untreated controls ($p < 0.005$)



AACR Poster Fig 5(C)