

## ASX Release

29 October 2026

### COMPLETE TUMOUR CLEARANCE IN GASTRIC CANCER ANIMAL STUDY

#### Highlights:

- **Arovella's CAR-iNKT cells demonstrated potent anti-tumour activity in a model of advanced gastric cancer**
- **Five out of seven (71%) animals treated with the cells survived and showed no sign of tumours after 60-days versus 0% for the control groups.**
- **Cytokine-armoured cells in a small sub-group eliminated tumours in all treated animals with 100% animal survival.**
- **Natural anti-tumour activity of iNKT cells was observed, delaying tumour growth even in the absence of a tumour-specific CAR, supporting the natural function of iNKT cells in tumour control.**
- **Data will be presented at the upcoming Consortium for iNKT Research and Therapy (CiRT) meeting at the University of Pennsylvania.**
- **The Board supports advancing the ALA-105 program to at-scale manufacturing and requesting formal FDA engagement early in the new year.**

Arovella Therapeutics Ltd (ASX: ALA) is pleased to announce positive results from an in vivo study evaluating its Claudin 18.2 (CLDN18.2)-targeted CAR invariant natural killer T (CAR-iNKT) cell therapy, ALA-105, in an animal model of advanced gastric cancer.

ALA-105 demonstrated impressive anti-tumour activity, with CLDN18.2-targeted CAR-iNKT cells leading to complete tumour clearance in five of seven animals (71%). In contrast, all control animals succumbed to tumours within 30-50 days. In a smaller sub-group of mice treated with IL-12-armoured CAR-iNKT cells tumours were eliminated in all treated animals and all animals survived the 60-day study. Animals in each group received a single dose of 4 million CAR-iNKT cells. The study was conducted at the University of North Carolina under Professor Gianpietro Dotti.

Arovella Acting CEO, Dr Nicole van der Weerden, said, "These results provide compelling in vivo validation of our CLDN18.2 CAR-iNKT program. The complete tumour clearance achieved with our IL-12-TM armoured CAR-iNKT cells highlights the potential of combining targeted CAR activity with cytokine armouring to overcome the challenges associated with treating solid tumours. Importantly, these findings are consistent with the strong in vitro efficacy we reported earlier this year and further strengthen our confidence."

Arovella Chairman, Mr David Williams, commented, "These data further demonstrate the versatility and power of our iNKT cell platform. The ability to achieve complete tumour clearance and survival in this challenging gastric cancer model reinforces the significant potential of our technology to address unmet needs in solid tumours. The results are so compelling that we have resolved to speed up a formal approach to the FDA. "

ALA-105 is Arovella's next-generation, allogeneic CAR-iNKT cell therapy being developed to target Claudin 18.2 (CLDN18.2), a tumour-associated protein expressed in a high proportion of gastric cancers and a subset of pancreatic cancers. By combining a CLDN18.2-directed CAR with the innate tumour-recognition properties

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of iNKT cells, ALA-105 is designed to selectively recognise and eliminate CLDN18.2-expressing cancer cells and address the substantial unmet need in these difficult-to-treat solid tumours.

Arovella's armouring technology, licensed from the University of North Carolina at Chapel Hill (UNC), is designed to strengthen the activity and persistence of iNKT cells. The technology produces the cytokine interleukin-12 attached to the membrane, concentrating its immune-stimulatory effects at the engineered cell surface. This enhances local anti-tumour activity while aiming to limit the systemic exposure associated with freely secreted IL-12. To learn more about Arovella's armouring technology see our whiteboard explainer video [here](#).

The study utilised a NUGC4-CLDN18.2 gastric cancer model in NSG mice, where CLDN18.2-positive tumour cells were introduced into the peritoneal cavity before treatment with iNKT cell therapies four days later. Animals were monitored for tumour burden using IVIS imaging and assessed for overall survival. Four treatment groups were evaluated: untreated control animals that received saline (PBS), iNKT cells expressing a CAR that targeted a protein not present on the tumour cells (control CAR), CLDN18.2-targeted CAR-iNKT cells, and CLDN18.2-targeted CAR-iNKT cells incorporating Arovella's membrane-tethered IL-12 (IL-12-TM) cytokine armouring technology.

In addition to the strong tumour control demonstrated by the CAR-iNKT cells, the study also confirmed that iNKT cells lacking a specific tumour-targeting CAR (iNKT cells with control CAR) possess an inherent ability to recognise and attack tumour cells and were able to delay gastric tumour growth compared with untreated controls. The activity is believed to be driven, at least in part, by natural tumour recognition pathways such as NKG2D-mediated targeting.

The findings build on Arovella's previously reported in vitro data and provide further evidence that CAR-iNKT cells may offer a highly effective approach for treating CLDN18.2-positive solid tumours, including gastric cancer.

These findings will guide ALA-105's clinical development strategy, with both unarmoured and IL-12-TM-armoured constructs under evaluation. Upcoming priorities include progressing manufacturing development and seeking FDA feedback on the proposed clinical pathway.

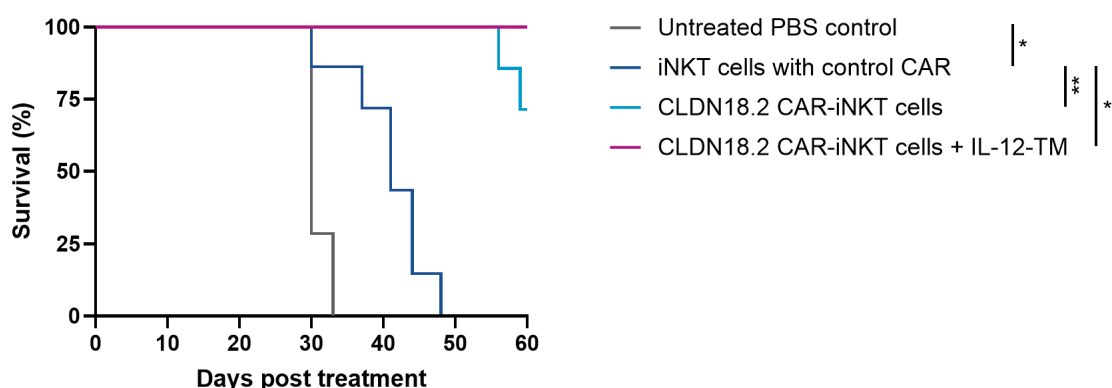


**Figure 1: Survival.** Kaplan-Meier survival curve of the intraperitoneal gastric cancer model for animals treated with CAR-iNKT cells or PBS. Log-rank with Holm-Bonferroni correction; \*  $p < 0.05$ , \*\*  $p < 0.005$ .

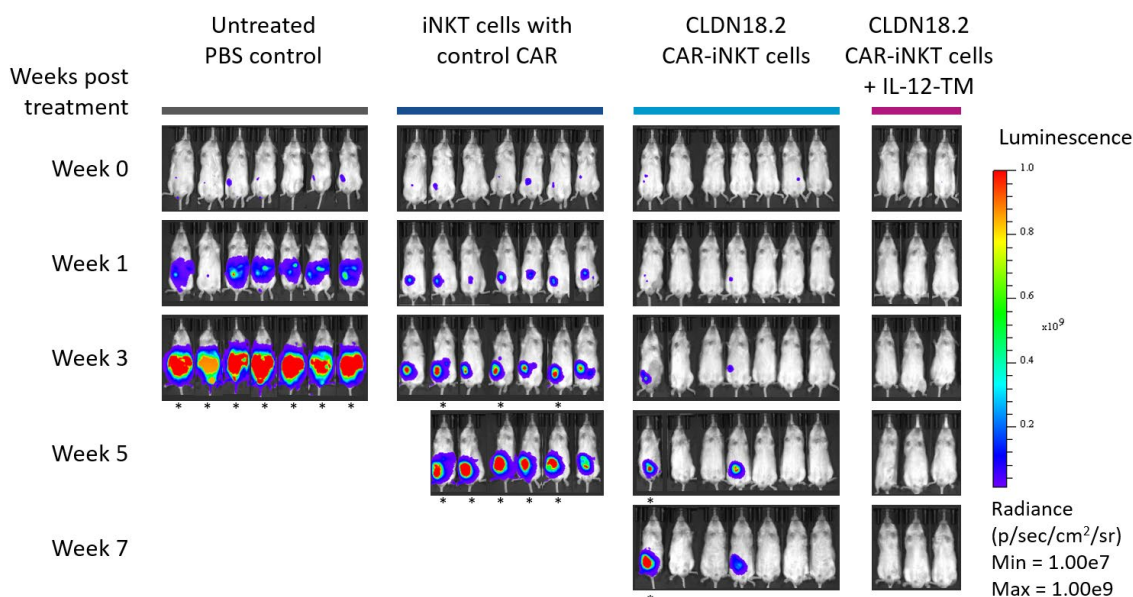


**Figure 2: Bioluminescent imaging of tumour progression.** Animals were imaged weekly using IVIS bioluminescent imaging to measure tumour burden of luciferase-expressing NUGC4-CLDN18.2 gastric cancer cells; images presented for weeks 1, 3, 5 and 7. Images marked with \* denote saturated images.

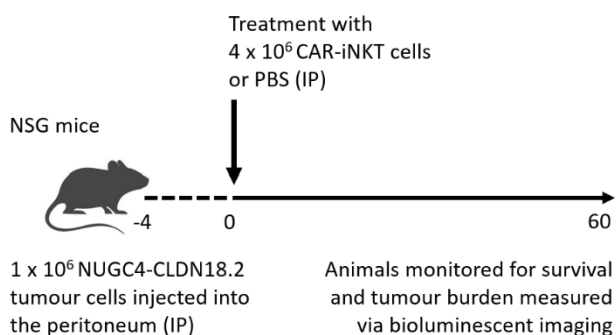


**Figure 3: Experimental Design.** Anti-tumour efficacy was evaluated using an intraperitoneal model of NUGC4-CLDN18.2 gastric cancer. Immunocompromised NSG mice were injected intraperitoneally (IP) with 1 million tumour cells and, following confirmation of tumour engraftment, were treated four days later with 4 million CAR iNKT cells (CLDN18.2 CAR-iNKT cells (n=7); CLDN18.2 CAR-iNKT cells with IL-12-TM (n=3); iNKT cells with a control CAR (n=7)) or PBS (n=7). Animals were monitored for 60 days post treatment for survival, and tumour burden was measured weekly using bioluminescent IVIS imaging.

These data will be presented at the upcoming Consortium for iNKT Research and Therapy (CiRT) meeting, which brings together leading physicians, scientists and companies focused on advancing iNKT-based therapies. The meeting will be hosted by the University of Pennsylvania, a globally recognised leader in cell therapy research and the institution where the pioneering clinical studies that led to the first FDA-approved CAR-T therapy, Kymriah, were conducted. Arovella looks forward to showcasing the potential of its iNKT platform, highlighting progress in its first-in-human clinical trial and solid tumour programs, and engaging with world leaders in the field to help advance the next generation of iNKT-based therapies.

*Release authorised by the Arovella Therapeutics Ltd Board of Directors.*

## ASX: ALA

Arovella Therapeutics Limited  
ACN 090 987 250



### FURTHER INFORMATION

#### Dr Nicole Van Der Weerden

Acting Chief Executive Officer

E [nvanderweerden@arovella.com](mailto:nvanderweerden@arovella.com)

M +61 407 039 983

#### David Williams

Chairman

E [dwilliams@kidder.com.au](mailto:dwilliams@kidder.com.au)

M + 61 414 383 594

### About Arovella Therapeutics Ltd

Arovella Therapeutics Ltd (ASX: ALA) is focused on developing its invariant natural killer T (iNKT) cell therapy platform licensed from Imperial College London to treat blood cancers, solid tumours, and autoimmune disease. 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 (iTCR) that targets glycolipid bound CD1d, another antigen found on the surface of several cancer types. ALA-101 has had its Investigational New Drug application (IND) accepted by the US FDA and 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 licenced from University of North Carolina 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; **CD1d** – Cluster of differentiation 1, which is expressed on some immune cells and cancer cells.

For more information, visit [www.arovella.com](http://www.arovella.com)

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