

## **ASX Release**

5 May 2025

## AROVELLA OPTIONS ADVANCED BAYLOR COLLEGE OF MEDICINE TECHNOLOGY TO ENHANCE INKT CELL PLATFORM

**Highlights:** 

- Arovella has obtained an exclusive Option from Baylor College of Medicine to license two novel chimeric antigen receptors (CARs) targeting solid tumours, including neuroblastoma and hepatocellular carcinoma
- If exercised, this provides Arovella with a dominant position in the iNKT cell space
- Both CARs have been studied in human clinical trials, reducing the need for extensive preclinical testing
- Substantial capital and resources have been allocated to develop the patent families to date
- The Option also includes manufacturing technology and iNKT cell genetic modifications that may enhance Arovella's CAR-iNKT cell platform
- The inventors, led by Professor Leonid Metelitsa, a leader in CAR-iNKT cell development, have previously guided two CAR-iNKT cell products into clinical trials in the US

**MELBOURNE, AUSTRALIA 5 May 2025:** Arovella Therapeutics Ltd (ASX: ALA), a biotechnology company focused on developing its invariant Natural Killer T (iNKT) cell platform to treat cancer, is pleased to announce that it has entered into an exclusive Option to license multiple patent families from Baylor College of Medicine to broaden the utility and enhance the performance of its iNKT cell platform (**Option**).

The patent families under Option cover technologies to integrate two additional chimeric antigen receptors (CARs) targeting solid tumours, as well as technology that may enhance the functionality of CAR-iNKT cells in the human setting. If Arovella proceeds with the licence, it will further differentiate Arovella across the iNKT cell sector and increase the barrier to entry for other companies developing iNKT cell therapeutics. If the Option is exercised, it would position Arovella as a dominant player in the iNKT cell space, which is already differentiated from other cell therapy types.

The two CARs included under the Option target GD2 and GPC3, clinically validated targets for solid tumours, have been studied in FDA IND-enabled clinical trials. Substantial capital and resources have been allocated toward the development of these CARs to date.

- **GD2** is found on the surface of numerous solid tumours including neuroblastoma, melanoma, glioma, small-cell lung carcinoma and various types of breast cancer.<sup>1</sup> It was also the focus of a recent study from researchers at Stanford University that demonstrated benefits for children and young adults with fast growing brain and spinal cord cancer.<sup>2</sup> The GD2 CAR included under the Option was recently used in an autologous CAR-iNKT trial for pediatric patients with neuroblastoma, where one patient displayed a durable complete response lasting greater than 12 months<sup>3</sup>.
- GPC3 is also considered a promising cancer target due to its high prevalence on the surface of

<sup>&</sup>lt;sup>1</sup> https://www.frontiersin.org/journals/immunology/articles/10.3389/fimmu.2024.1371345/full

<sup>&</sup>lt;sup>2</sup> https://www.cancer.gov/news-events/cancer-currents-blog/2025/car-t-cell-therapy-gd2-diffuse-midline-gliomas

<sup>&</sup>lt;sup>3</sup> https://www.nature.com/articles/s41591-023-02363-y



numerous cancers, particularly hepatocellular carcinoma (HCC; liver cancer) and its limited presence in healthy tissues.<sup>4</sup> HCC continues to be a leading cause of cancer deaths globally.<sup>5</sup> The CAR under Option was recently published in Nature, demonstrating that when used in CAR-T cells, it yields promising results for patients with HCC.<sup>6</sup>

Under a licence agreement, Arovella would look to incorporate these CARs into its proprietary manufacturing process to develop allogeneic CAR-iNKT products targeting GD2 and GPC3.

Under the Option, Arovella also gains access to technologies developed to improve the functionality and impact that CAR-iNKT cells have in treating cancer. Arovella will examine how to incorporate the improvements into its current and future product pipeline.

One of the leading inventors of the patents under Option is Professor Leonid Metelitsa, Director of the Center for Advanced Innate Cell Therapy (AICT) at the Texas Children's Cancer Center, Baylor College of Medicine. He is a recognised authority in developing CAR-iNKT cells, having published extensively on the development and use of CAR-iNKT cells for blood cancers and solid tumours. At Baylor College of Medicine, his group, in close collaboration with the Center for Cell and Gene Therapy (CAGT) led by Professor Helen Heslop, has taken two CAR-iNKT cell programs into clinical trials through the US FDA IND pathway and established manufacturing protocols for producing GMP-grade material for phase 1 clinical trials.

Arovella's CEO and Managing Director, Dr Michael Baker, commented: "Arovella believes in the potential of CAR-iNKT cells, and the team is excited by the prospect of working with Baylor to examine the potential for combining our technologies to enhance the CAR-iNKT platform. The potential to access two new solid tumour targets is an excellent opportunity for Arovella to leverage the progress it has made in developing its proprietary manufacturing process."

Professor Metelitsa commented: "I have spent much of my career understanding how to unlock the potential of CAR-iNKT cells for cancer treatment. We believe that CAR-iNKT cells have great potential across a range of disease areas, and we have tested CAR-iNKT cells in both blood cancers and solid tumours. We are delighted to be in discussion with Arovella to potentially expand our work using CAR-iNKT cells to target tumours of high unmet need."

There is no fee payable by Arovella for the grant of the Option. The exclusive Option has a term of six months, during which time Baylor College of Medicine must not offer any third party any rights (or options to obtain rights) in the patents and associated intellectual property for use in the same field. During the Option term, the parties will negotiate in good faith the intended terms of a formal licence agreement. If Arovella exercises the Option during the Option term, the parties will finalise those terms and formalise them under a definitive licence agreement, within 60 days of the exercise (which can be extended by a further 180 days if agreement cannot be reached during the 60-day period). There is no certainty that Arovella will determine to exercise the Option, or that a definitive licence agreement can be agreed between the parties and executed if Arovella does exercise the Option.

<sup>&</sup>lt;sup>4</sup> https://www.tandfonline.com/doi/full/10.1080/14728222.2024.2416975?src=

<sup>&</sup>lt;sup>5</sup> https://www.nature.com/articles/s41575-019-0186-y

<sup>&</sup>lt;sup>6</sup> https://www.nature.com/articles/s41586-024-08261-8



This announcement has been authorised for release by the Company's Board of Directors.

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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. Arovella is also expanding into solid tumour treatment through its CLDN18.2-targeting technology licensed from Sparx Group. iNKT cells also contain an invariant T cell receptor (iTCR) that targets  $\alpha$ -GalCer bound CD1d, another antigen found on the surface of several cancer types. ALA-101 is being developed as an allogeneic cell therapy, which means it can be given from a healthy donor to a patient.

**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

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