

ASX: ALA

Arovella Therapeutics Limited
ACN 090 987 250



ASX Release

27 October 2026

FIRST PATIENT DOSED WITH ALA-101

Highlights:

- **Arovella achieves major milestone with first patient dosed in its phase 1 clinical trial of ALA-101, Arovella's "off-the-shelf" cell therapy for blood cancers**
- **Trial will evaluate the safety, tolerability, pharmacology and preliminary efficacy of ALA-101 in patients with certain blood cancers**

Arovella Therapeutics Ltd (ASX: ALA) is pleased to announce the achievement of a major milestone with the dosing of the first patient in its first-in-human phase 1 clinical trial. The SAPPHIRE study (ALA-101-001; NCT07518329) is an open-label, multi-centre, dose-escalation and expansion trial evaluating ALA-101, Arovella's allogeneic off-the-shelf CD19 CAR-iNKT cell therapy, in patients with relapsed or refractory CD19-positive non-Hodgkin lymphoma and leukaemia.

The patient received ALA-101 following standard lymphodepleting chemotherapy at The Alfred under the supervision of Dr Salvatore (Sam) Fiorenza.

Lead Investigator, Dr Sam Fiorenza, commented, "Dosing the first patient with ALA-101 is a key milestone in the development of a new class of cell therapies for patients with relapsed or refractory B cell malignancies. Despite advances in treatment, many patients either relapse following standard therapies or are unable to access currently available autologous CAR-T therapies. We look forward to evaluating the safety and potential clinical activity of ALA-101 and contributing to the advancement of this novel allogeneic CAR-iNKT cell approach."

Dr Nicole van der Weerden, Acting Chief Executive Officer of Arovella, commented, "Dosing the first patient is a milestone and the culmination of several years of focused scientific, manufacturing, regulatory and clinical development. It is immensely satisfying to see the work of our team and collaborators translate into the delivery of our novel cell therapy to a patient for the first time. ALA-101 has been designed to overcome key limitations of conventional CAR-T therapies by using healthy donor-derived iNKT cells that can be manufactured in advance and supplied when needed. This trial will provide important insights into the safety, expansion, persistence and B cell-depleting activity of ALA-101 and support the development of Arovella's broader CAR-iNKT platform across blood cancers, solid tumours and autoimmune diseases. We are deeply grateful to the patient, the clinical team and everyone who has contributed to reaching this milestone."

David Williams, Chairman, said "Our killer T cell technology licenced from Imperial College London is a game changer. Our treatment is manufactured and sitting on a shelf ready for use, derived from healthy donors. The current treatment requires a patient's own cells, a process that is costly and time-consuming."

Release authorised by the Arovella Therapeutics Ltd Board of Directors.

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FURTHER INFORMATION

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About the SAPPHIRE trial

The initial dose escalation part of the trial will assess the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary efficacy of a single dose of ALA-101. During dose escalation, dosing will be staggered in accordance with regulatory requirements as part of IND approval to ensure adequate safety review between patients. Initial data from the trial are expected to be available early in CY2027.

The study incorporates a backfill Bayesian Optimal Interval (BF-BOIN) design to enable adaptive dose escalation and efficient allocation of participants to dose levels with an acceptable emerging safety profile as they become available. Backfill enrolment will commence only once a dose level has been reviewed and confirmed acceptable from a safety perspective. The dose expansion/backfill part of the trial will further characterise the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy of ALA-101. Generating additional data at dose levels with acceptable safety profiles is intended to provide a robust basis for selecting the most appropriate dose to advance into a phase 2 study, informed by the overall balance of safety and preliminary activity. It also provides flexibility to expand enrolment in specific disease subtypes based on emerging data, allowing promising signals of clinical activity to be explored in greater depth within the trial.

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 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 1d, which is expressed on some immune cells and cancer cells.

For more information, visit www.arovella.com

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