

ASX: ALA

Arovella Therapeutics Limited
ACN 090 987 250



ASX Release

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THE PATH TO FIRST PATIENT DOSING

Highlights:

- **Patients being screened for eligibility, with first-patient dosing expected in October — a major milestone for Arovella**

Arovella Therapeutics Ltd (ASX: ALA) advises that screening is underway to identify patients for its phase 1 ALA-101 study. First patient dosing is now expected to occur towards the end of October 2026.

The first-in-human trial will evaluate ALA-101 in patients with relapsed or refractory CD19-positive non-Hodgkin lymphoma and leukaemia. Potential participants are first identified by their treating clinicians based on their diagnosis and medical history, then provided with information about the study and asked to give informed consent before trial-specific screening begins. Screening involves a detailed assessment against the protocol's eligibility criteria, including clinical examinations and laboratory tests. Patients undergo this process at The Alfred Hospital, with enrolment dependent on confirmation that all eligibility criteria and clinical requirements have been met. If a patient does not pass screening for any reason, or decides not to participate, they cannot be enrolled and the identification, consent and screening process must begin again. Since there is only a single dosing slot available at the beginning of the trial, patients are screened one at a time for ethical reasons.

The revised dosing timetable is not a reflection of patient availability or demand for the study. Instead, it reflects the practical requirements associated with meeting the strict eligibility requirements in a first-in-human cellular therapy trial.

Acting Chief Executive Officer, Dr Nicole van der Weerden, said, "The level of interest from clinicians and patients in the ALA-101 study is exciting. However, identifying patients who meet all eligibility criteria and completing the screening process is prescribed and takes time. There is no shortage of patients requiring treatment and we have everything in place to dose the first patient once eligibility is confirmed."

Release authorised by the Board of Directors of Arovella Therapeutics.

FURTHER INFORMATION

Dr Nicole van der Weerden

Acting Chief Executive Officer

E nvanderweerden@arovella.com

M +61 407 039 983

David Williams

Chairman

E dwilliams@kidder.com.au

M + 61 414 383 594

About Arovella Therapeutics Ltd

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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 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.

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