ASX Release

25 June 2026

FIRST-IN-HUMAN TRIAL

Highlights:

- **On top of US FDA IND acceptance and TGA acknowledgement, Arovella now has ethics approval for it's first-in-human clinical trial of ALA-101**
- **ALA-101 is Arovella's lead allogeneic CAR-iNKT cell therapy for patients with blood cancer**
- **The Alfred in Melbourne is lead clinical site, with Dr Salvatore "Sam" Fiorenza Lead Investigator**
- **Site initiation activities have commenced with first patient dosing expected in September, after each site's Research Governance Office (RGO) approval**

> "First-in-human cannot happen fast enough for me because there is a long list of patients with nowhere else to go." David Williams, Chairman

Arovella Therapeutics Ltd (ASX: ALA), is a clinical-stage biotechnology company focused on developing its "off-the-shelf" invariant Natural Killer T (iNKT) cell therapy platform. Arovella has received ethics approval to commence its phase 1 first-in-human clinical trial of ALA-101, it's lead allogeneic CD19-directed CAR-iNKT cell therapy for patients with relapsed or refractory lymphomas and leukemias.

The phase 1 trial, is an open label, first-in-human dose-escalation and expansion/backfill study designed to evaluate the safety, tolerability and preliminary anti-tumour activity of ALA-101 in patients with certain blood cancers.

The Alfred in Melbourne is the lead clinical site, with experienced CAR-T cell therapy clinician Dr Salvatore "Sam" Fiorenza Lead Investigator. The trial is expected to involve up to seven clinical sites across Australia and New Zealand, with broader site activation activities also underway at Epworth Healthcare, St Vincents Sydney, The Mater Brisbane and Royal Adelaide Hospital.

Ethics approval has been obtained from The Alfred and Bellberry Human Research Ethics Committees, providing central ethics support for participating study sites. The approval follows Arovella's U.S. Food and Drug Administration (FDA) Investigational New Drug (IND) application clearance, and Therapeutic Goods Administration (TGA) Clinical Trial Notification (CTN) acknowledgement. Completing the key regulatory and ethics approvals required to initiate the study.

Arovella remains on track to commence first patient dosing in Q3 CY2026.

The Lead Investigator, Dr Sam Fiorenza commented, "There is a substantial unmet need for patients with relapsed or refractory haematological cancers, particularly for patients who have exhausted existing treatment options. As clinician researchers, finding novel therapies that will result in better outcomes for our patients is the hope, and we are pleased to be part of the evaluation of this new approach."

Acting Chief Executive Officer, Dr Nicole van der Weerden, said: "First-in-human is an important step in our transition to a clinical-stage company and is the culmination of the disciplined approach we have taken in regulatory, manufacturing and clinical readiness. We are preparing to complete site initiation and first patient dosing. This milestone means we can evaluate the potential of our allogeneic CAR-iNKT platform for patients with significant unmet medical need and generate clinical data important for patients, clinicians and shareholders. I anticipate exciting and important data to come from this trial"

Lead investigator Dr Sam Fiorenza and Chairman David Williams on Sky Business:
https://www.youtube.com/watch?v=-uQFPEsGihA&t=6s

Release authorised by Arovella Limited Board of Directors.

FURTHER INFORMATION

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NOTES TO EDITORS:

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 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. 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.

For more information, visit www.arovella.com