ASX Release

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TGA CONFIRMS ALA-101 CLINICAL TRIAL TO PROCEED IN AUSTRALIA VIA CTN SCHEME

Highlights:

- **Arovella's ALA-101-001 phase 1 clinical trial to progress in Australia via the Clinical Trial Notification (CTN) pathway**
- **The CTN pathway is a more streamlined and predictable process for trial initiation (compared with Clinical Trial Approval (CTA) pathway)**
- **Arovella will now finalise Human Research Ethics Committee (HREC) approvals and complete site initiation before the commencement of patient recruitment**

MELBOURNE, AUSTRALIA 16 March 2026: Arovella Therapeutics Ltd (ASX: ALA), a biotechnology company focused on developing its invariant Natural Killer T (iNKT) cell therapy platform, is pleased to announce that the Therapeutic Goods Administration (TGA) has confirmed that the Company's planned Australian Phase 1 clinical trial of ALA-101, its allogeneic CD19-targeting CAR-iNKT cell therapy, can proceed under the Clinical Trial Notification (CTN) Scheme.

The TGA's confirmation follows the recent clearance of Arovella's Investigational New Drug application (IND) by the U.S. Food and Drug Administration (FDA), supported by a comprehensive preclinical and manufacturing data package, to initiate a first-in-human clinical trial for ALA-101 in both Australia and the United States.

Under the CTN Scheme, the conduct of the clinical trial is primarily overseen by the Human Research Ethics Committee (HREC) and the relevant clinical investigators, and the TGA is notified of the trial prior to commencement. This approach provides a more streamlined and predictable process for initiating clinical trials compared with the CTA pathway.

Conducting the study under the CTN Scheme provides several advantages:

- Efficient regulatory pathway for early-phase clinical trials in Australia
- Ability to rapidly initiate sites following HREC approval and site governance
- Opportunity to enrol Australian patients into a first-in-human allogeneic CAR-iNKT therapy study

With the CTN pathway confirmed, Arovella intends to:

- Finalise HREC approvals for Australian sites;
- Complete site initiation activities;
- Begin patient recruitment once institutional approvals are in place.

Arovella's CEO and Managing Director, Dr Michael Baker, commented, "This marks an important milestone for the ALA-101 program. By pairing the IND with Australia's favourable clinical environment, it enables the team to conduct clinical trials more efficiently and cost-effectively. We are pleased to receive this positive feedback from the TGA and to be accelerating towards the clinic for ALA-101."

The Company will provide further updates as the clinical program progresses.

In Australia, advanced therapies such as cell and gene therapies frequently proceed via the Clinical Trial Approval (CTA) pathway, which involves direct review of the investigational product dossier by the Therapeutic Goods Administration (TGA) prior to trial commencement. The CTA pathway is commonly used for novel biological products where regulators require additional oversight before authorising clinical studies. CTA submissions typically involve a formal TGA review process and associated regulatory timelines, which can extend study start-up periods and may involve requests for additional information or clarifications before approval is granted.

Release authorised by Arovella Limited 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. 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 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; **αGalCer** – 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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