ASX Release

December 30, 2025

AROVELLA FILES INVESTIGATIONAL NEW DRUG (IND) APPLICATION WITH THE U.S. FDA FOR FIRST-IN-HUMAN PHASE 1 TRIAL OF ALA-101

Highlights:

- **IND application submitted to the U.S. FDA for ALA-101**
- **First-in-human Phase 1 study planned in patients with CD19-positive haematological malignancies**
- **IND acceptance will permit clinical trial initiation in Australia and the United States**

MELBOURNE, AUSTRALIA 30 December 2025: 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 it has submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for its lead cell therapy candidate, ALA-101, an allogeneic CAR-iNKT cell therapy targeting CD19-positive non-Hodgkin's lymphoma (NHL) and leukaemias.

The IND submission represents a major operational and regulatory milestone for Arovella, enabling the Company to progress ALA-101 towards its first-in-human Phase 1 clinical trial, pending FDA clearance. FDA review of the IND application typically occurs within 30 days. The Company will update the market following notification from the Agency.

ALA-101 is Arovella's lead allogeneic cell therapy product derived from iNKT cells engineered to express a CD19-specific chimeric antigen receptor (CAR). An off-the-shelf product offers several potential advantages over first-generation CAR-T approaches, including, a manufacturing process that is scalable and cost-efficient and enables "off-the-shelf" dosing to reduce the time to treatment for patients and improves access.

The planned Phase 1 clinical study will assess the safety, tolerability, pharmacokinetics, and preliminary anti-tumour activity of ALA-101 in patients with relapsed/refractory CD19-positive NHL and leukaemias. Obtaining an active IND is a critical step for Arovella as it enables the company to conduct its Phase 1 trial in Australia via the Clinical Trial Notification (CTN) scheme rather than the lengthier Clinical Trial Application (CTA) pathway. It also enables Arovella to open clinical trial sites in the U.S.

Dr Michael Baker, Chief Executive Officer and Managing Director of Arovella Therapeutics, said: "Filing the IND for ALA-101 is an excellent milestone for Arovella, and we look forward to receiving the feedback from the FDA. It reflects the strength of our scientific and manufacturing foundations and marks the Company's transition toward becoming a clinical-stage biotechnology company."

Release authorised by the Arovella Therapeutics 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; **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

This announcement contains certain statements which may constitute forward-looking statements or information ("forward-looking statements"), including statements regarding negotiations with third parties and regulatory approvals. These forward-looking statements are based on certain key expectations and assumptions, including assumptions regarding the actions of third parties and financial terms. These factors and assumptions are based upon currently available information, and the forward-looking statements herein speak only of the date hereof. Although the expectations and assumptions reflected in the forward-looking statements are reasonable in the view of the Company's directors and management, reliance should not be placed on such statements as there is no assurance that they will prove correct. This is because forward-looking statements are subject to known and unknown risks, uncertainties and other factors that could influence actual results or events and cause actual results or events to differ materially from those stated, anticipated or implied in the forward-looking statements. These risks include but are not limited to: uncertainties and other factors that are beyond the control of the Company; global economic conditions; the risk associated with foreign currencies; and risk associated with securities market volatility. The Company assumes no obligation to update any forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements, except as required by Australian securities laws and ASX Listing Rules.