ASX Release

January 29, 2026

AROVELLA'S IND FOR ALA-101 ACCEPTED BY THE U.S. FOOD AND DRUG ADMINISTRATION

Highlights:

- **IND application accepted by the U.S. FDA for ALA-101**
- **IND acceptance enables Arovella to progress the first-in-human clinical trial for ALA-101**
- **The accepted IND provides the framework for all future CAR-iNKT cell programs under development, including ALA-105 and other solid tumour products**

MELBOURNE, AUSTRALIA 29 January 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 U.S. Food and Drug Administration (FDA) has accepted its investigational new drug (IND) application for ALA-101 to commence first-in-human clinical trials.

The IND acceptance represents a key operational and regulatory milestone for Arovella, enabling the Company to commence first-in-human phase 1 clinical trials of ALA-101 in patients with CD19-positive non-Hodgkin's lymphoma (NHL) and leukaemia. Importantly, securing the IND 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.

The acceptance of the IND by the U.S. FDA provides regulatory validation of ALA-101's preclinical package, manufacturing process, and overall clinical development plan, which is a major de-risking step for the Company. Importantly, Arovella anticipates that the successful ALA-101 IND application will provide a framework that can be leveraged in the development of pipeline products, including ALA-105 for the treatment of gastric cancer, and potentially for new technologies targeting neuroblastoma and hepatocellular carcinoma currently being negotiated for license from Baylor College of Medicine.

Dr Michael Baker, Managing Director and Chief Executive Officer of Arovella Therapeutics, said: "The team has done an amazing job capturing all of the experimental data and related technical information required for a successful IND submission. To have it accepted by the U.S. FDA demonstrates the capability of our team and the Company's selected partners, including our manufacturer, Cell Therapies Pty Ltd. We have initiated the activities required for our Human Research Ethics Committee (HREC) submission and clinical trial site selection and activation. Now that the IND is accepted, we look forward to accelerating these activities and taking ALA-101 into the first-in-human phase 1 clinical trial. We are hopeful that ALA-101 will bring meaningful benefit to patients enrolled in the study who would otherwise have no remaining treatment options."

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

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.