ASX Release

7 August 2024

POSITIVE PRE-IND FEEDBACK FROM FDA FOR ALA-101

Highlights:

- **Positive pre-Investigational New Drug (pre-IND) meeting response from the US Food and Drug Administration (FDA) has been received by Arovella for the development of ALA-101 in first-in-human clinical trials for lymphoma and leukaemia**
- **FDA Feedback provides clear and achievable requirements for the submission of an IND for ALA-101 with IND submission expected in early Q1 CY2025**
- **The pre-IND guidance includes a review of Arovella's Chemistry, Manufacturing and Controls (CMC) program, plan for nonclinical safety and efficacy studies, and proposed phase 1 clinical trial design**

MELBOURNE, AUSTRALIA 7 August 2024: 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 received positive feedback from the FDA during a pre-IND meeting in the lead up to its phase 1 study of ALA-101 as a treatment for CD19+ blood cancers.

Feedback from the pre-IND meeting, which was held via teleconference with the FDA, supported Arovella's development plans to commence a phase 1, first-in-human clinical trial. The meeting provided a clear path forward to submitting an IND for ALA-101, with no major changes proposed for the development program. Allogeneic CAR-iNKT cell therapy manufacturing is highly complex and very few allogeneic CAR-iNKT cells have a received an IND acceptance to start first-in-human trials, so pre-IND feedback was critical to ensure that Arovella's development plan for ALA-101 aligns with FDA expectations. The FDA guidance included a review of Arovella's CMC program, a plan for nonclinical safety and efficacy studies, and the proposed phase 1 clinical trial design.

Based on the precise information provided by the FDA, Arovella expects to file its IND for ALA-101 in early Q1 CY2025.

Arovella's Chief Executive Officer and Managing Director, Dr Michael Baker, commented, "The valuable and positive feedback we received from the FDA was excellent and aligns clearly with our development plans for ALA-101. For a complex therapeutic like off-the-shelf CAR-iNKT cells, our team has done a commendable job reaching this key milestone. We look forward to receiving acceptance for our IND and executing our plan to advance ALA-101 into the clinic over the coming months. Due to the platform nature of Arovella's CAR-iNKT cells, the learnings for ALA-101 throughout the IND application process can be applied to our additional solid tumour programs, such as ALA-105."

Release authorised by the Managing Director and Chief Executive Officer of Arovella Therapeutics Limited.

Dr Michael Baker
Chief Executive Officer & Managing Director
Arovella Therapeutics Ltd
Tel +61 (0) 403 468 187
investor@arovella.com

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.