ASX Release

28 October 2025

POSITIVE FDA TYPE D MEETING OUTCOME

Highlights:

- **Positive feedback on reagent testing requirements during Type D meeting with US FDA**
- **Arovella expects to file its IND application for ALA-101 in the current quarter**

MELBOURNE, AUSTRALIA 28 October 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 today held a Type D meeting with the United States Food and Drug Administration (FDA) and received positive feedback on testing requirements for a critical reagent used in its CAR-iNKT manufacturing process. The agency provided clear guidance on testing requirements for the reagent and Arovella has already completed much of the testing required.

The Company is now working to generate the additional data requested by the FDA and expects to file its IND application for ALA-101 before the end of CY25.

Arovella's CEO and MD, Dr Michael Baker, commented, "We are pleased with the feedback from the FDA which confirms our pathway to IND. Taking the time to engage with the agency has provided us with valuable and constructive feedback, enabling us to move forward with confidence in submitting our IND application this quarter and progressing ALA-101 into clinic early in 2026."

ALA-101 is a next-generation "off-the-shelf" CAR-iNKT cell therapy that targets CD19+ B cell lymphomas and leukaemias. CD19 is an antigen found on the surface of many blood cancers. Certain blood cancers also express CD1d, which when bound to a glycolipid, can be recognised by iNKT cells, making CAR-iNKT cells dual targeting.

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; **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

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.