ASX Release

29 October 2025

AROVELLA PROGRESSES ALA-101 PROGRAM WITH APPOINTMENT OF PHASE 1 CRO

Highlights:

- **Arovella appoints SAPRO to support its phase 1 clinical trial for ALA-101**
- **Phase 1 trial to assess safety, tolerability, pharmacokinetics (PK) and preliminary efficacy in patients with CD19-positive non-Hodgkin's lymphoma and leukaemia**
- **Dose escalation expected to begin in early 2026**

MELBOURNE, AUSTRALIA 29 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 initiated start-up activities for its upcoming phase 1 trial for ALA-101 and appointed SAPRO as its contract research organisation (CRO) partner. SAPRO was selected after an extensive and rigorous selection process conducted by the Arovella management team.

Arovella's CEO and MD, Dr Michael Baker, commented, "After positive feedback from FDA during our recent Type D meeting, we are excited to initiate start-up activities for the phase 1 clinical trial and are delighted to have found an excellent partner in SAPRO. We appreciate the SAPRO team's dedication to our trial and look forward to dosing our first patient in 2026. The data we obtain from this first-in-human trial informs not only the development of ALA-101, but also directly translates to Arovella's solid tumour programs."

Kim Steel, Managing Director, SAPRO wrote, "We're thrilled to be chosen by Arovella as their Trial Pathway Partner (TPP) and CRO on the ALA-101 clinical program, a truly innovative cell therapy targeting CD19-positive malignancies. At SAPRO, our passion lies in helping pioneering biotech companies translate complex science into meaningful clinical outcomes. The ALA-101 study represents a major step forward in Australian-led immunotherapy development across the globe, and we're proud to contribute our expertise to help bring this important treatment closer to patients. We bring our deep regulatory knowledge, operational agility and scientific rigour needed to accelerate ALA-101 toward patients who need it most."

The first-in-human phase 1 study is an open-label, dose escalation and dose expansion trial targeting CD19-positive non-Hodgkin's lymphoma and leukemia and initial clinical sites are anticipated to be located across Australia and New Zealand. The initial, dose escalation part of the trial will assess the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary efficacy of a single dose of ALA-101 and establish the maximum tolerated dose (MTD) for the expansion phase. A Bayesian design will be employed to enable efficient dose escalation and to maximise the likelihood that patients are enrolled at a safe and effective dose. The dose expansion part of the trial will further characterise the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy of ALA-101. The commencement of the trial is subject to human research ethics committee (HREC) approval and local institutional approvals.

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

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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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