ASX Release

7 September 2026

CLINICAL MANUFACTURING BATCH SUCCESSFULLY RELEASED FOR DOSING AND FIRST CLINICAL SITE ACTIVATED

Highlights:

- **ALA-101 is Arovella's "off-the-shelf" cell therapy for blood cancers**
- **First clinical batch of ALA-101 has been successfully manufactured and now released for dosing in first-in-human study**
- **First clinical trial site activated at The Alfred in Melbourne**
- **Patient screening and enrolment can start, with first patient dosing expected later this month**

Into the clinic

Arovella Therapeutics Ltd (ASX: ALA) is pleased to advise that it has manufactured and released the first clinical batch of ALA-101 and activated The Alfred as the first clinical trial site for its human phase 1 study.

Site activation at The Alfred follows completion of ethics and governance approvals and site initiation. With a site open and product in hand, Arovella expects to dose its first patient this month.

Oils ain't oils

ALA-101 is a donor-derived cell therapy made in batches from healthy donor cells rather than each patient's own cells. This has the potential to be delivered to the patient faster and manufactured at a lower cost than conventional therapies derived from a patient's own blood. This is a key differentiator for Arovella, for patient health, and for speed of treatment.

Successful clinical manufacturing is a critical step toward demonstrating the key advantages of Arovella's platform of off-the-shelf availability, rapid access to treatment, and the potential to overcome many of the manufacturing and cost limitations associated with using a patient's own cells. The manufacturing process utilised for ALA-101 is expected to be broadly applicable across other products developed using Arovella's platform.

Arovella Acting CEO, Dr Nicole van der Weerden, said, "Releasing our first clinical batch is a significant achievement and key milestone. Manufacturing our product to clinical standard, meeting FDA requirements and having it ready for patients is a game changer and demonstrates that our platform works in practice. With our lead site now activated and product available, our focus turns to screening and enrolling the first patient." A video of Dr van der Weerden discussing this announcement can be viewed here.

Arovella Chairman, Mr David Williams, added, "Activating our first site and releasing our first clinical batch are very important and move us out of the lab and into patients. However, the most important thing is to be able to manufacture cells in bulk without relying on the patient's cells. Arovella's off-the-shelf product shall be cheaper, faster and available when patients need it." A short video of Mr Williams discussing this announcement can be viewed here.

The Company will update the market as further sites are activated when it doses the first patient.

Release authorised by the Arovella Limited Board of Directors.

FURTHER INFORMATION

Dr Nicole Van Der Weerden
Acting Chief Executive Officer
E nvanderweerden@arovella.com
M +61 407 039 983

David Williams
Chairman
E dwilliams@kidder.com.au
M + 61 414 383 594

NOTES TO EDITORS:

About Arovella Therapeutics Ltd

Arovella Therapeutics Ltd (ASX: ALA) is focused on developing its invariant natural killer T (iNKT) cell therapy platform licensed from Imperial College London to treat blood cancers, solid tumours, and autoimmune disease. 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 has had its Investigational New Drug application (IND) accepted by the US FDA and 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