

ASX Release

7 October 2026

SECOND CLINICAL BATCH RELEASED FOR IMMEDIATE PATIENT USE

Highlights:

- A second clinical batch of ALA-101 has been manufactured and released, proving the reproducibility and scalability of our manufacturing process
- Supply is now sufficient to complete dose escalation and commence patient dose expansion in blood cancers
- A third batch expected before year-end and is anticipated to provide sufficient material to complete the phase 1 trial
- Off-the-shelf manufacturing solves a CAR-T bottleneck by producing and storing treatment material in advance of patient treatment, enabling greater patient access and speed of treatment
- An additional site has been activated at the Epworth Hospital and more are coming soon in Sydney and Brisbane
- We now have off the shelf product and hospital sites ready to go and support patient screening and recruitment and dosing

Arovella Therapeutics Ltd's (ASX: ALA) scalable manufacturing process for its donor-derived CAR-iNKT therapy, enables clinical material to be manufactured and stored ahead of patient treatment. The two batches released so far provide sufficient material to complete dose escalation and begin dose expansion. A third batch, expected to be released by end December, is anticipated to provide sufficient material to complete the phase 1 trial of 46 patients over five hospital sites.

Scalable off-the-shelf manufacturing addresses a recognised CAR-T bottleneck

Manufacturing is a bottleneck for conventional autologous CAR-T therapies, which require product to be made using each patient's own cells. This complex and individualised process contributes to the high cost of treatment, creates manufacturing and logistical challenges and can leave patients waiting for treatment.

Arovella's approach uses healthy donor-derived invariant natural killer T (iNKT) cells to manufacture in advance and not requiring a patient's own cells. ALA can produce multiple treatment doses and store and ready for use off the shelf.

This approach has the potential to eliminate manufacturing-related delays, simplify treatment logistics and broaden access for patients.

Screening for eligible patients and the addition of new clinical hospital sites, means the company can expand the trial quickly once the first patient is dosed this month.

New clinical sites being activated

Arovella is also progressing activation of additional clinical trial sites. The Epworth Hospital in Melbourne has been activated and St Vincent's Hospital in Sydney and Mater Hospital in Brisbane are expected to be activated soon. These sites will broaden access for eligible patients and support recruitment and execution.

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ASX: ALA

Arovella Therapeutics Limited
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Dr Nicole van der Weerden, Acting CEO of Arovella Therapeutics, said: “We are at a defining milestone — treating the first patient. As patient screening quickens, we will have enough product on the shelf to treat the 46 patients. Our second clinical batch underscores both the power of Arovella’s off-the-shelf approach and the robustness and reproducibility of our scalable GMP manufacturing process.

By manufacturing from healthy donor cells in advance, we are building a bank of off-the-shelf clinical material and the need to manufacture separate product for every patient. We now have sufficient clinical material to complete dose escalation and begin dose expansion.”

Chairman David Williams said: “We are ready to go and will soon have enough product on the shelf to dose all 46 patients supported by five exceptional hospital sites as we move towards dosing expected in late October.”

Release authorised by the Board of Directors of Arovella Therapeutics.

FURTHER INFORMATION

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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; **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