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Arovella Nears First Patient Dosing with ALA-101

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Company Snapshot

Company	Arovella Therapeutics Limited (ASX: ALA)
Lead asset	ALA-101, a donor-derived CAR-iNKT cell therapy directed at CD19
Lead indication	Relapsed or refractory CD19-positive non-Hodgkin's lymphoma and certain leukaemias
Shares on issue	1,208.9m
Share Price (15 Sep 2026)	$0.059
Market Capitalisation (AUD)	71.3m
Net Cash (30 Jun 2026)	14.4m

Source: Iress 15 September 2026

CAR-T has shown that a patient's own immune cells can be turned into a powerful cancer treatment. The catch is that every dose has to be made individually. In traditional CAR-T therapy you take a patient's own immune cells, re-engineer them in a lab so they recognise a marker that sits on the surface of certain cancer cells, and put them back in. The immune cells can then target and kill the cancer cells. Seven CAR-T products are FDA-approved and selling in the US. Carvykti from Johnson & Johnson and Legend Biotech alone did about US$1.9 billion in net sales in FY2025, treating more than 10,000 cumulative patients.

The problem isn't that CAR-T therapy doesn't work. The problem is how they are made. The cells come from each individual patient, so every single dose is a separate manufacturing run. The patient has to be well enough to give cells, then well enough to wait several weeks while the batch is made and tested, and plenty of sick people are not well enough to wait. The cost sits where you would expect for a bespoke product: Kymriah launched with a US list price of US$475,000. Autologous products, meaning ones made from the patient's own cells, still account for most of the market.

Arovella's answer is to make the product in batches from healthy donors instead, so it sits frozen in a hospital waiting for the patient rather than the other way around. That is what "allogeneic" and "off-the-shelf" mean. Plenty of companies are chasing the same idea. What makes Arovella unique is the cell type it has picked.

A Different Approach to CAR-T

Arovella licensed a platform built on invariant natural killer T cells, or iNKT cells, from Imperial College London. iNKT cells already recognise and kill some cancer cells on their own, they help recruit other parts of the immune system, they change the environment around a tumour, and, critically, they do not appear to cause graft versus host disease, where the donor's immune cells attack the recipient's own healthy tissue. That last point is the one that makes the off-the-shelf model workable, because it is what lets you take cells from a stranger and give them to a patient without matching.

Bolted onto those cells is a CAR, or chimeric antigen receptor, which is essentially a homing device the company engineers into the cell, so it hunts a specific target. Because the manufacturing process is largely

the same regardless of which CAR you install, Arovella potentially has a platform rather than a single drug: one process, many possible products.

Almost nobody else is doing specifically what ALA is doing. Most cell-therapy companies use conventional T cells or NK cells. There are only a handful of companies seriously developing iNKT-based therapies, and even fewer developing CAR-iNKT products.

ALA-101

ALA-101 is the lead product. It uses iNKT cells from healthy donors, engineered to carry a CAR that targets CD19, a protein found on B cells and on the blood cancers that come from them. It is aimed at patients with relapsed or refractory non-Hodgkin's lymphoma and certain leukaemias, meaning people whose disease has come back or never responded in the first place.

In laboratory models the company reports ALA-101 outperforming conventional CAR-T cells against cancer cell lines carrying both CD19 and CD1d, killing cancer cells quickly and extending survival in mice with lymphoma and leukaemia.

The sequence over the last two years:

- July 2024: positive pre-IND meeting with the US FDA confirming the path to a Phase 1.
- March 2025: Completed a $15 million placement at $0.125 per share.
- March 2025 quarter: manufacturing process transferred into a GMP-compliant environment, meaning a facility built and audited to make material fit to give to humans.
- December 2025: IND application filed with the FDA.
- January 2026: IND accepted, followed by TGA confirmation the trial could run in Australia under the Clinical Trial Notification scheme.
- June 2026: ethics approval from The Alfred and Bellberry human research ethics committees.
- September 2026: first clinical batch manufactured and released, The Alfred activated as the first site, screening and enrolment able to begin.

ALA-101 Enters the Clinic

ALA recently announced 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. The Phase 1 trial is a first-in-human, open-label dose escalation study with a dose expansion and backfill component, in patients with relapsed or refractory CD19-positive non-Hodgkin's lymphoma and certain leukaemia subtypes.

Dr Salvatore Fiorenza, an experienced CAR-T clinician, is lead investigator. Up to seven sites are planned across Australia and New Zealand, with activation work underway at Epworth Healthcare, St Vincent's Sydney, Mater Hospital Brisbane and Royal Adelaide Hospital.

First patient dosing is expected this month.

What the Trial Will Test

Safety and tolerability. This is a first-in-human study, so the primary job is to establish that donor-derived iNKT cells can be given to patients without unacceptable toxicity. The two things to watch are cytokine release syndrome, an aggressive inflammatory reaction that CAR-T therapies are known for, and any sign of graft versus host disease. Arovella's whole thesis rests on iNKT cells not causing the latter, so a clean safety profile here is not a box-tick, it is the thesis being tested.

Early signs of effect. The study also measures pharmacokinetics and pharmacodynamics, meaning how long the cells persist and what they do while they are there, plus preliminary efficacy.

B-cell depletion. The trial will specifically measure whether ALA-101 can find and eliminate CD19-positive B cells in patients. A whole class of autoimmune diseases, including lupus, myositis, stiff person syndrome, generalised myasthenia gravis and systemic sclerosis, is driven by misbehaving B cells. Several published studies have now shown CD19-targeting CAR-T therapies producing meaningful responses in patients with severe refractory autoimmune disease and allowing some of them to come off lifelong immune-suppressing drugs.

Where Positive Data Could Lead

With these trial results the plan is to use ALA-101 data to open two doors at once. The first is autoimmune disease, where the company intends to use the same product, the same manufacturing process and the same emerging clinical dataset rather than build a new platform. The second is solid tumours, where a clean safety readout from ALA-101 would validate the core iNKT manufacturing platform shared with ALA-105.

ALA-105

ALA-105 is Arovella's second program which targets claudin 18.2, a protein that shows up on stomach and pancreatic tumour cells, present in roughly 40% to 70% of gastric cancers and up to 60% of pancreatic ductal adenocarcinomas.

Solid tumours are much harder than blood cancers for cell therapies, because the cells have to physically get into a tumour and keep working in a hostile environment. Arovella's response is what it calls IL-12-TM armouring, essentially building a booster signal into the cell so it keeps expanding rather than exhausting itself. The preclinical results reported in April 2026 showed that across four successive rounds of tumour cells thrown at them, the armoured CAR-iNKT cells still killed more than 97% of pancreatic and 82% of gastric tumour cells. The data was presented at AACR in San Diego on 20 April 2026 and at ISCT in Dublin on 7 May 2026.

The caveat is the obvious one. Those are cells in a dish. Mouse models for gastric and pancreatic cancer have been established, with in vivo efficacy studies planned as the next real test.

Next Steps

Near term, the list is short and specific.

1. Complete dosing of the first patient.
2. Activate the remaining Australian and New Zealand sites.
3. Work through the dose escalation.
4. Report the B-cell depletion data.
5. Finish the animal efficacy studies for ALA-105.

Current state of the market

Seven CAR-T products are approved in the US: Carvykti from Johnson & Johnson, Yescarta and Tecartus from Gilead's Kite, Breyanzi and Abecma from Bristol Myers Squibb, Kymriah from Novartis and Aucatzyl from Autolus Therapeutics.

Carvykti did ~US$1.9 billion in net trade sales in 2025 and is running well ahead of that pace in 2026, with US$597 million in the March quarter and US$657 million in the June quarter, up 62% and 50% on the prior year. Breyanzi did US$1.4 billion in 2025, up 82% year on year, and picked up an FDA approval in marginal zone lymphoma in December 2025. Kymriah, the first one ever approved, did US$381 million in 2025, down 14% on the prior year.

Two features of that market matter for Arovella. Every one of the seven approved products is made one patient at a time, and no off-the-shelf CAR-T has been approved anywhere, so the bottleneck Arovella is attacking is the entire market as it stands today. Pricing sits in the hundreds of thousands of dollars per dose. US list prices in 2025 ranged from about US$462,000 for Tecartus to US$594,000 for Kymriah, with 2022–2025 price growth of roughly 3% to 7% a year across the products. Making the product in batches from donors rather than one patient at a time should cut the cost of each dose materially, though whether that reaches the patient as a lower price or the manufacturer as a wider margin is a choice nobody has yet had to make. The larger prize is the patients who never get treated at all: the ones too sick to wait weeks for a batch, or whose own cells cannot be made into one.

Recent US$1b+ CAR-T Acquisitions

Deal activity across CAR-T and next-generation cell therapy has been intense, including allogeneic and in vivo approaches designed to sidestep patient-by-patient manufacturing.

Acquirer / Target	Announced	Headline value	What was bought
AstraZeneca / Gracell Biotechnologies	Dec 2023	US$1.2bn	Phase 1b/2. Autologous BCMA/CD19 dual-targeting CAR-T for myeloma, plus the FasTCAR rapid manufacturing platform
Roche / Poseida Therapeutics	Nov 2024	Up to US$1.5bn	Phase 1. Allogeneic CAR-T programs for myeloma and B-cell cancers; the closest structural comparable to Arovella
AstraZeneca / EsoBiotec	Mar 2025	Up to US$1.0bn (US$425m upfront)	Phase 1. In vivo lentiviral platform; lead asset a BCMA CAR-T for myeloma
AbbVie / Capstan Therapeutics	Jun 2025	Up to US$2.1bn	Phase 1. In vivo CD19 CAR-T for B-cell autoimmune disease
Bristol Myers Squibb / Orbital Therapeutics	Oct 2025	US$1.5bn	Preclinical. Circular RNA in vivo platform with a CD19 asset for autoimmune disease
Eli Lilly / Orna Therapeutics	Feb 2026	Up to US$2.4bn	Preclinical. In vivo CD19 CAR-T for autoimmune disease
Gilead / Arcellx	Feb 2026	US$7.8bn (+ US$5 per share contingent)	Registration. Autologous BCMA CAR-T for myeloma, application under FDA review with a decision due December 2026

Eli Lilly / Kelonia Therapeutics	Apr 2026	Up to US$7.0bn (US$3.25bn upfront)	Phase 1. In vivo BCMA CAR-T for myeloma; largest in vivo deal to date

Buyers are paying ten figures for companies with assets that are preclinical or barely into Phase 1, so the premium is on platform and mechanism rather than on data. Acquisitions are being made in both oncology and autoimmune diseases, so the money is not chasing one indication so much as one bottleneck, which is getting an engineered cell into a patient without a bespoke manufacturing run.

An important point is that most of the 2025 and 2026 targets are in vivo companies, which is where a patient's own immune cells are re-engineered inside their own body. This is a different answer to the bottleneck from Arovella's off-the-shelf donor cells. The deal closest to Arovella's modality is Roche's purchase of Poseida.

Upcoming Catalysts

Catalyst	Expected timing	Significance
First patient dosed with ALA-101	September 2026	The company becomes clinical stage in fact rather than in name.
Activation of remaining Australian and New Zealand sites	Ongoing	Determines enrolment speed. Up to seven sites planned.
Initial safety and tolerability observations from dose escalation	H1 CY27 [estimate]	The core test of whether donor-derived iNKT cells can be given without graft versus host disease.
B-cell depletion data from the Phase 1	Follows initial dosing cohorts	The read-through to autoimmune indications. Arguably the highest-value output of the study.
In vivo efficacy results for armoured CLDN18.2 CAR-iNKT cells (ALA-105)	Coming months per company guidance	First animal proof of concept for the solid tumour program.

Indicative timing only. Events may be delayed, modified or may not occur.

ASX Peer Comparisons

The table below sets out listed Australian companies developing CAR-T therapies.

Company (Ticker)	Lead asset, indication and delivery	Clinical stage	Market capitalisation (AUD, m)
Arovella Therapeutics (ALA)	ALA-101, CD19 CAR-iNKT, allogeneic, r/r NHL and leukaemia	Phase 1 starting	71.3

Prescient Therapeutics (PTX)	OmniCAR, modular/universal CAR-T enabling platform (lead asset is PTX-100, which is unrelated to cell therapy)	Preclinical	69.4
Imugene (IMU)	azer-cel, CD19 CAR-T, allogeneic, r/r B-cell malignancies	Phase 1b	25.8
AdAlta (1AD)	EW-001, MSLN-targeted, PD-1-armoured CAR-T, autologous, advanced mesothelioma / solid tumours	Clinical stage in China; Australian/US program pre-IND	9.6

NHL = Non-Hodgkin lymphoma

Imugene is the closest comparison. It is the only other ASX company running a donor-derived CD19-directed cell therapy in patients and it is further along at Phase 1b.

Global Peer Comparisons

The table below sets out listed international companies developing donor-derived cell therapies, engineered or otherwise.

USD:AUD = 1.40:1.00

Company (Ticker)	Lead asset, indication and delivery	Clinical stage	Market capitalisation (AUD, m)
Allogene Therapeutics (NASDAQ: ALLO)	cema-cel, CD19 CAR-T, allogeneic; high-risk large B-cell lymphoma following first-line therapy	Phase 2 (ALPHA3)	861.0
Century Therapeutics (NASDAQ: IPSC)	CNTY-101, CD19 CAR-iNK, iPSC-derived allogeneic; B-cell-mediated autoimmune diseases	Phase 1/2 (CARAMEL)	507.0
Nkarta (NASDAQ: NKTX)	NKX019, CD19 CAR-NK, allogeneic; B-cell-mediated autoimmune diseases	Phase 1/2 (Ntrust-1 and Ntrust-2)	292.8
Caribou Biosciences (NASDAQ: CRBU)	vispa-cel (formerly CB-010), CD19 CAR-T, allogeneic; r/r B-cell non-Hodgkin lymphoma / 2L LBCL	Phase 1; pivotal Phase 3 planned	193.6
Adicet Bio (NASDAQ: ACET)	prula-cel (formerly ADI-001), CD20 gamma-delta CAR-T, allogeneic; autoimmune diseases	Phase 1	127.1
MiNK Therapeutics (NASDAQ: INKT)	agenT-797, unmodified allogeneic iNKT cells, acute lung injury and solid tumours	Phase 2	83.5

Source: company disclosures. Iress 15 September 2026

MiNK Therapeutics is the most useful reference point. It is the only other listed iNKT pure play, it is further into the clinic with a randomised Phase 2 running, and it is capitalised at US$60 million. MiNK uses unmodified iNKT cells while Arovella adds a CAR.

Closing thoughts

Dosing the first patient will tell us whether iNKT cells engineered with a CAR behave in a human being the way they have behaved in the models Arovella has run. Specifically, whether they can be given from a stranger without the recipient's body and the donated cells turning on each other. The claims the company makes about being off-the-shelf, cheaper and faster than conventional CAR-T sit on top of that single assumption.

That is why it matters more than a typical Phase 1 start. Most first-in-human studies test a molecule. This one tests a manufacturing model and a business case at the same time. Success would validate both the lead program and the off-the-shelf model underpinning Arovella's wider pipeline, creating scope for a material re-rating.

Register for future research updates

Disclosure: Prenzler Group employees own fully paid ordinary shares in Arovella Therapeutics Limited (ASX: ALA).

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