

**ASX Release**

27 September 2022

**NEW PRECLINICAL TRIAL OF AROVELLA'S iNKT CELL THERAPY AND IMUGENE'S  
onCARlytics (CF33-CD19) PLATFORM TO EXPLORE POTENTIAL IN SOLID TUMOURS  
(CORRECTION)**

**MELBOURNE, AUSTRALIA & SYDNEY, AUSTRALIA, 27 September 2022:** Arovella Therapeutics Ltd (ASX: ALA), a biotechnology company focused on developing its invariant Natural Killer T (iNKT) cell platform for cancer treatment, and Imugene Limited (ASX: IMU), a clinical stage immune-oncology company, yesterday announced a collaboration to test Arovella's CAR19-iNKT (ALA-101) cell therapy with Imugene's onCARlytics platform to seek and destroy solid tumours.

The announcement included an incorrect attribution of Imugene's onCARlytics CD19 oncolytic virus licensed from the City of Hope. This has been corrected in the attached announcement.

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

For further information please contact:

**Dr Michael Baker**  
**CEO & Managing Director**  
**Arovella Therapeutics Ltd**  
Tel +61 (0) 403 468 187  
mbaker@arovella.com

**Leslie Chong**  
**Managing Director and CEO**  
**Imugene Ltd**  
info@imugene.com

**Media Enquiries**

Matt Wright  
matt@nwrcommunications.com.au

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**NEW PRECLINICAL TRIAL OF AROVELLA'S iNKT CELL THERAPY AND IMUGENE'S onCARlytics (CF33-CD19) PLATFORM TO EXPLORE POTENTIAL IN SOLID TUMOURS****HIGHLIGHTS:**

- Arovella's CAR19-iNKT cell therapy will be combined with Imugene's onCARlytics (CF33-CD19) platform to target solid cancers in a pre-clinical trial.
- This trial will explore the potential of expanding the use of ALA-101 in solid tumours, which pose significant unmet need and account for more than 90% of all diagnosed cancers.
- onCARlytics is a CD19-expressing oncolytic virus that enters tumour cells and forces them to express the CD19 protein on the cell surface, presenting a target for CD19 targeting therapies.

**MELBOURNE, AUSTRALIA & SYDNEY, AUSTRALIA, 26 September 2022:** Arovella Therapeutics Ltd (ASX: ALA), a biotechnology company focused on developing its invariant Natural Killer T (iNKT) cell platform for cancer treatment, is pleased to collaborate with clinical stage immune-oncology company Imugene Limited (ASX: IMU), using its onCARlytics platform. This will test Arovella's CAR19-iNKT (ALA-101) cell therapy with Imugene's onCARlytics platform to seek and destroy solid tumours. The read out from the preclinical studies performed through the collaboration is expected in H1 2023.

Arovella's lead iNKT product, ALA-101, contains a Chimeric Antigen Receptor (CAR) that targets tumour cells producing CD19 on their surface. Typically, CD19 expression is on the cell surface of blood cancers. Imugene's onCARlytics platform enables solid tumour cancers to express CD19 on their surface, which creates the opportunity to use ALA-101 to seek and destroy the solid tumour cells. Currently, ALA-101 is being developed for CD19-producing blood cancers. Working with Imugene raises the possibility of using ALA-101 to treat solid tumour cancers.

Imugene is evaluating a range of CD19 targeting therapies in combination with onCARlytics of which Arovella's ALA-101 will be included, allowing Arovella to benchmark its iNKT therapy for the treatment of solid tumours. Initial pre-clinical data from Arovella demonstrates that ALA-101 cells outperform conventional T cells in haematological malignancies that produce CD19 and CD1d. Achieving compelling data in this study would open up a new therapeutic area of potential indications in solid tumours for Arovella's iNKT cell therapy products.

Solid tumours represent 90% of diagnosed cancer cases<sup>1</sup>, and as of 2021, the solid tumour market was valued at US\$210 billion<sup>2</sup>.

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<sup>1</sup><https://www.cancer.gov/types/common-cancers>

<sup>2</sup><https://www.databridgemarketresearch.com/reports/global-solid-tumors-market#:~:text=Data%20Bridge%20Market%20Research%20analyses,period%20of%202022%20to%202029.>

Imugene's CEO and MD, Leslie Chong, commented, "Our onCARlytics platform opens up the possibility to treat solid tumours with existing CD19 targeting drugs. Solid tumours account for more than 90% of cancers diagnosed, and our technology has the potential to change the outcomes for these patients. We are excited to see how Arovella's iNKT cell platform and other drugs in our trial perform on the back of our platform. We are delighted to work with another Australian-based biotechnology company focussing on cancer treatment."

Arovella's CEO and MD, Dr Michael Baker, commented, "We are excited to collaborate with Imugene to evaluate potential of our iNKT product in combination with their onCARlytics product for treatment of solid tumours. Imugene's onCARlytics is one of the most promising products to be developed for solid tumours. We believe strongly in the unique capability of our iNKT program and look forward to seeing how ALA-101 performs in these models. Arovella is excited by the prospect of expanding its use of its iNKT cell therapy platform to treat solid tumours."

The research partnership is material to Arovella as it includes development of Arovella's iNKT cell therapy platform licensed from Imperial College London (see ASX announcement dated 18 June 2021) with Imugene's onCARlytics CD19 oncolytic virus licensed from the City of Hope. The combination has the potential to be a novel approach to treating certain solid tumour cancers.

### **Key Terms of the Agreement**

The research collaboration agreement is effective as of 26 September 2022 and has an initial term of twelve months. The strategic collaboration may be terminated upon completion of the research, or by mutual agreement. Arovella will fund the preclinical studies from its planned research budget, and no further funding is required for the initial research completed through the partnership. Currently each party has full intellectual property (IP) rights (patents) to their individual background technology. In the event new IP is generated from the research collaboration (each a "Combination Invention"), the parties shall discuss in good faith the filing, prosecution, maintenance, enforcement, defense of any patent applications thereto, as well as each party's right to use, such Combination Invention. After the results from this research agreement are known and can be quantified, the parties will negotiate in good faith (and without obligation) whether to jointly develop or commercialise on the outcomes of the strategic collaboration on commercially reasonable terms.

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**CEO & Managing Director**  
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mbaker@arovella.com

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### **About Arovella Therapeutics Ltd**

Arovella Therapeutics Ltd (ASX: ALA) is a biotechnology company focused on developing therapies to treat human diseases. Arovella's two focus areas are oncology and conditions that impact the central nervous system. Arovella is developing its invariant natural killer T (iNKT) cell therapy platform from Imperial College London to treat blood cancers. Arovella is also expanding its DKK1-peptide targeting technology licenced from MD Anderson and used in conjunction with its iNKT cell therapy platform. The Company is also developing low-risk oral sprays to reformulate existing pharmaceuticals. The potential benefits of administering drugs through the oral mucosa (i.e. cheeks, tongue, gums and palate) include ease of use, lower dosage, reduced side effects and faster response time. Arovella's product pipeline consists of an oral spray for the platelet-lowering drug anagrelide to treat metastatic disease in the background of high platelets and ZolpiMist™, a first-in-class oral spray of zolpidem tartrate to treat short-term insomnia. ZolpiMist is approved by the FDA and the TGA and is marketed in the USA. Arovella has rights to the product outside of the US and Canada. Other products in development include oral sprays to treat migraine headaches, motion sickness, and drug-resistant epilepsy.

For more information, visit [www.arovella.com](http://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.

### **About Imugene (ASX:IMU)**

Imugene is a clinical stage immuno-oncology company developing a range of new and novel immunotherapies that seek to activate the immune system of cancer patients to treat and eradicate tumours. Our unique platform technologies seek to harness the body's immune system against tumours, potentially achieving a similar or greater effect than synthetically manufactured monoclonal antibody and other immunotherapies. Our product pipeline includes multiple immunotherapy B-cell vaccine candidates and an oncolytic virotherapy (CF33) aimed at treating a variety of cancers in combination with standard of care drugs and emerging immunotherapies such as CAR T's for solid tumours. We are supported by a leading team of international cancer experts with extensive experience in developing new cancer therapies with many approved for sale and marketing for global markets.

Our vision is to help transform and improve the treatment of cancer and the lives of the millions of patients who need effective treatments. This vision is backed by a growing body of clinical evidence and peer-reviewed research. Imugene is well funded and resourced, to deliver on its commercial and clinical milestones. Together with leading specialists and medical professionals, we believe Imugene's immuno-oncology therapies will become foundation treatments for cancer. Our goal is to ensure that Imugene and its shareholders are at the forefront of this rapidly growing global market.