

ASX ANNOUNCEMENT 1 December 2022

# COMPELLING PRECLINICAL DATA FOR KAZIA'S EVT801 PUBLISHED IN PEER-REVIEWED CANCER RESEARCH JOURNAL

**Sydney, 1 December 2022** – Kazia Therapeutics Limited (NASDAQ: KZIA; ASX: KZA), an oncology-focused drug development company, is pleased to announce the publication of positive preclinical data for EVT801, a clinical-stage drug candidate currently in a clinical trial for multiple forms of cancer.

The publication, by Michael Paillasse and colleagues, summarizes a large body of preclinical research conducted principally by scientists at Evotec SE and at the University Cancer Institute of Toulouse - Oncopole over a period of several years. It is now published in *Cancer Research Communications*, a recently-launched journal published by the American Association of Cancer Research (AACR). The data formed the basis of Kazia's in-licensing of EVT801 from Evotec in 2021 and has since supported transition of the compound into an ongoing phase I clinical trial in patients with advanced solid tumors.

## **Key Points**

- EVT801 is a selective inhibitor of vascular endothelial growth factor receptor 3 (VEGFR3). VEGFs and VEGFRs are well-validated cancer drug targets with multiple FDA-approved products directed to them, but a more selective VEGFR3 inhibitor, such as EVT801, may result in better tolerability and less development of resistance to therapy.
- EVT801 was confirmed in preclinical studies to be a potent and selective inhibitor of VEGFR3, with activity in the low nanomolar range. The drug was shown to inhibit the formation of lymphatic vessels *in vitro*, confirming its intended primary mode of action.
- In vivo (animal) experiments showed EVT801 to be more active than both pazopanib (Votrient<sup>®</sup>, Novartis) and sorafenib (Nexavar<sup>®</sup>, Bayer) in the tumor models under investigation.
- EVT801 combined with immune checkpoint inhibitors in mouse models of several tumor types showed strongly synergistic activity, with the combination performing better than either drug alone. Immune checkpoint inhibitors are widely used in many

Board of Directors Mr Iain Ross Chairman, Non-Executive Director Mr Bryce Carmine Non-Executive Director Mr Steven Coffey Non-Executive Director Dr James Garner Chief Executive Officer, Managing Director cancers, and the class includes drugs such as pembrolizumab (Keytruda<sup>®</sup>, Merck), nivolumab (Opdivo<sup>®</sup>, Bristol Myers Squibb), and ipilimumab (Yervoy<sup>®</sup>, Bristol Myers Squibb).

"These data demonstrate the substantial potential of EVT801 as a cancer therapeutic," stated Dr Michael Paillasse, lead author of the publication. "EVT801 has been shown to act exactly as intended: by impacting the vasculature in and around the tumor. In addition, the evidence of synergy with immunotherapy is persuasive, and we see a considerable opportunity to combine the drug with immune checkpoint inhibitors in clinical trials."

"We are grateful that the results of this public-private translational research initiative have been appreciated by the editors and reviewers of *Cancer Research Communications*. We will now focus on the clinical development," said Professor Jean-Pierre Delord, co-author and CEO of the IUCT – Oncopole.

"We are delighted to see this exciting and comprehensive body of work now published in a leading peer-reviewed journal," said Dr James Garner, Chief Executive Officer of Kazia. "The data supports our decision last year to in-license EVT801, and clearly points to the future development strategy for the drug. Our collaboration with the Evotec team has already been extremely fruitful, and we look forward to continuing to work together on this very promising drug candidate."

The publication may be accessed via the journal website at <a href="https://aacrjournals.org/cancerrescommun/article/2/11/1504/711325/Targeting-Tumor-Angiogenesis-with-the-Selective">https://aacrjournals.org/cancerrescommun/article/2/11/1504/711325/Targeting-Tumor-Angiogenesis-with-the-Selective</a>.

## **Phase I Clinical Trial Progressing**

EVT801 is currently the subject of an ongoing phase I clinical trial as monotherapy in patients with advanced solid tumors (NCT05114668). The study is progressing as planned, with patients currently being dosed within the anticipated therapeutic range. It is expected that initial data from this study will be available in 1H CY2023.

## For More Information, Please Contact:-

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#### About Kazia Therapeutics Limited

Kazia Therapeutics Limited (NASDAQ: KZIA; ASX: KZA) is an oncology-focused drug development company, based in Sydney, Australia.

Our lead program is paxalisib, a brain-penetrant inhibitor of the PI3K / Akt / mTOR pathway, which is being developed to treat multiple forms of brain cancer. Licensed from Genentech in late 2016, paxalisib is or has been the subject of ten clinical trials in this disease. A completed phase II study in glioblastoma reported promising signals of efficacy in 2021, and a pivotal study for registration, GBM AGILE, is ongoing, with final data expected in CY2023. Other clinical trials are ongoing in brain metastases, diffuse midline gliomas, and primary CNS lymphoma, with several of these having reported encouraging interim data.

Paxalisib was granted Orphan Drug Designation for glioblastoma by the US FDA in February 2018, and Fast Track Designation for glioblastoma by the US FDA in August 2020. In addition, paxalisib was granted Rare Pediatric Disease Designation and Orphan Designation by the US FDA for DIPG in August 2020, and for atypical teratoid / rhabdoid tumours (AT/RT) in June 2022 and July 2022, respectively.

Kazia is also developing EVT801, a small-molecule inhibitor of VEGFR3, which was licensed from Evotec SE in April 2021. Preclinical data has shown EVT801 to be active against a broad range of tumour types and has provided compelling evidence of synergy with immuno-oncology agents. A phase I study commenced recruitment in November 2021.

For more information, please visit <u>www.kaziatherapeutics.com</u> or follow us on Twitter @KaziaTx.

## About IUCT-Oncopole

The IUCT-Oncopole, a cancer care, research and training center in Toulouse, combines the expertise of 1,800 professionals on a single site labeled "Comprehensive Cancer Center". It combines several state-of-the-art clinical facilities for the treatment of cancer with a world-class research infrastructure, on an integrated campus that brings together public and private stakeholders, including industrial partners. The IUCT-Oncopole, which includes the Claudius Regaud Institute (ICR) and several teams from the Toulouse University Hospital, treats more than 10,000 new patients every year, and more than one in eight patients is enrolled in clinical studies. Visit <u>https://news.iuct-oncopole.fr/</u> for more.

This document was authorized for release to the ASX by James Garner, Chief Executive Officer, Managing Director.

#### **Forward-Looking Statements**

This announcement may contain forward-looking statements, which can generally be identified as such by the use of words such as "may," "will," "estimate," "future," "forward," "anticipate," or other similar words. Any statement describing Kazia's future plans, strategies, intentions, expectations, objectives, goals or prospects, and other statements that are not historical facts, are also forward-looking statements, including, but not limited to, statements regarding: the timing for results and data related to Kazia's clinical and preclinical trials, and Kazia's strategy and plans with respect to its programs, including paxalisib and EVT801. Such statements are based on Kazia's expectations and projections about future events and future trends affecting its business and are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the

forward-looking statements, including risks and uncertainties: associated with clinical and preclinical trials and product development, related to regulatory approvals, and the related to the impact of global economic conditions. These and other risks and uncertainties are described more fully in Kazia's Annual Report, filed on form 20-F with the SEC, and in subsequent filings with the SEC. Kazia undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required under applicable law. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this announcement.