



1 May 2024

KAZIA REPORTS SUCCESSFUL STAGE 1 COMPLETION OF THE EVT801 PHASE 1 CLINICAL TRIAL IN ADVANCED CANCER PATIENTS

Sydney, May 1, 2024 – Kazia Therapeutics Limited (NASDAQ: KZIA), a biotechnology company specialising in oncology, is pleased to announce that the Safety Review Team (SRT) of the EVT801 Phase 1 clinical trial has concluded that the primary and secondary objectives of stage 1 of the trial have successfully been met.

Consisting of the trial’s lead investigators, independent medical monitor, and key members from Kazia Therapeutics, the SRT has reviewed all preliminary (non-final) safety and pharmacokinetic (PK) data, and unanimously agreed that the maximal tolerated dose (MTD) has been reached at 500mg twice a day (BID). Under the condition that continuous monotherapy administration will be used in future clinical trials, 400mg BID was identified as the starting recommended phase 2 dose (RP2D).

A total of 26 patients received EVT801 across six dosing cohorts ranging from 50mg daily to 500mg BID. In general, EVT801 was tolerated across all doses with the majority of toxicities being mild to moderate and transient in nature. Eleven different cancer types (ex. colon, renal cell, pancreatic) were enrolled in the study, with advanced ovarian cancer being the most prevalent (11 patients). These 11 patients had an average age of 67 years (range: 56-76) and a median time from diagnosis of nine years. Forty-six percent (46%) of the ovarian cancer patients had stable disease or better for at least three cycles of EVT801 therapy.

EVT801 is a highly selective small molecule VEGFR3 tyrosine kinase inhibitor targeting tumour angiogenesis. Unlike traditional angiokinase inhibitors, we believe based on preclinical data that EVT801 has favorable immune activity (reduces immunosuppressive cells and no impact on CD3+ T-cells proliferation) and stabilizes tumor blood vessels, minimizing hypoxia and therefore decreases the potential for metastatic spread. The Phase 1 EVT801 monotherapy dose-finding trial targets patients with histologically confirmed advanced or metastatic solid tumours that are unresponsive to standard treatment, or for whom no standard treatment is available or appropriate.

Kazia Therapeutics CEO, Dr. John Friend said: “We are extremely pleased that the primary and secondary end points of stage 1 of the Phase 1 clinical trial have been met. The signals of clinical activity, especially in patients with advanced ovarian cancer are highly encouraging as we continue to progress the clinical development program for EVT801 as a potential first-in-class VEGFR3 inhibitor. With a median survival time of less than 4 years, there is a large unmet need for new therapies in patients with high-grade serous ovarian cancer.”

The Phase 1, open label study is designed to assess the safety, tolerability, and PK of EVT801 in patients with advanced or metastatic solid tumors unresponsive to standard treatment, or for whom no standard treatment is available or appropriate.

Primary Objective:	<ul style="list-style-type: none">• To evaluate the safety and tolerability of EVT801 in subjects with advanced or metastatic solid tumours.• To determine the MTD and / or a RP2D of EVT801 when administered daily to subjects with advanced or metastatic solid tumours.
Secondary Objectives:	<ul style="list-style-type: none">• To characterise the PK of EVT801 following administration in an oral capsule formulation.



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| | <ul style="list-style-type: none">• To identify active metabolites of EVT801 in plasma.• To determine preliminary anti-tumour activity of EVT801 via assessment of overall response rate. |
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We look forward to sharing the final stage 1 data and next development steps at an upcoming scientific conference in the second half of 2024.

About Kazia Therapeutics Limited

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

Our lead program is paxalisib, an investigational 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 2 study in glioblastoma reported early signals of clinical activity in 2021, and a pivotal study in glioblastoma, GBM AGILE, is ongoing, with final data expected in 1H2024. 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 FDA in February 2018, and FTD for glioblastoma by the FDA in August 2020. Paxalisib was also granted FTD in July 2023 for the treatment of solid tumour brain metastases harboring PI3K pathway mutations in combination with radiation therapy. In addition, paxalisib was granted Rare Pediatric Disease Designation and Orphan Drug Designation by the FDA for diffuse intrinsic pontine glioma in August 2020, and for atypical teratoid / rhabdoid tumours 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 evidence of synergy with immuno-oncology agents. Stage one of the Phase I study has been completed and preliminary data is anticipated in CY2024.

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

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, Kazia's strategy and plans with respect to its programs, including paxalisib and EVT801, the potential benefits of EVT801 as a VEGFR3 inhibitor and the potential market opportunity for EVT801. Such statements are based on Kazia's current 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 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 United States Securities and Exchange Commission. 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.

This announcement was authorized for release by Dr John Friend, CEO.