

ASX RELEASE 1 August 2022

## KAZIA PROVIDES PROGRESS UPDATE ON GBM AGILE PIVOTAL STUDY

**Sydney, 1 August 2022** – Kazia Therapeutics Limited (NASDAQ: KZIA; ASX: KZA), an oncology-focused drug development company, announced today a progress update on the GBM AGILE pivotal study (NCT03970447), a global adaptive clinical trial platform designed to evaluate multiple therapies for glioblastoma, to which paxalisib commenced enrolment in January 2021.

Kazia has been advised by the Global Coalition for Adaptive Research (GCAR), the sponsor of the study, that the first stage of the paxalisib arm has completed recruitment. The treatment arm did not meet pre-defined criteria for continuing to a second stage, and patients enrolled in the first stage of the paxalisib arm will therefore continue on treatment as per protocol, and in follow-up, until completion of the final analysis, which Kazia anticipates receiving in 2H CY2023, as previously disclosed.

Given that completion of recruitment has now occurred, the study will not open to the paxalisib arm in Germany or China. Kazia will work with its licensing partner to determine the way forward in China, given that country's general requirement for local data to register a new pharmaceutical product.

All Kazia personnel continue to be blinded to efficacy and safety data from the ongoing study, as required by regulatory authorities, and so the company remains unable to provide analysis or interpretation of the study until follow-up is complete and final data is available.

Kazia CEO, Dr James Garner, commented, "GBM AGILE was designed as an adaptive study, with the potential to follow a range of different paths to completion. Today's news defines the remaining trajectory of the study, with modestly positive implications for both costs and timelines, and with some specific consequences for regulatory strategy in China. It does not allow us to draw any meaningful inferences about the outcomes of the study, and indeed it is critical for regulatory purposes that we remain blinded to the evolving data. We look forward to reporting final results in 2H CY2023, as currently planned. In the meantime, we are excited by some of the emerging data in diffuse intrinsic pontine glioma (DIPG) and brain metastases, which have become increasingly important areas of focus for the company and look forward to sharing more detail on those activities in due course."

#### **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

# 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.

In Australia:

Our lead program is paxalisib, a brain-penetrant inhibitor of the PI3K / Akt / mTOR pathway, which is being developed to treat glioblastoma, the most common and most aggressive form of primary brain cancer in adults. Licensed from Genentech in late 2016, paxalisib commenced recruitment to GBM AGILE, a pivotal study in glioblastoma, in January 2021. Seven additional studies are active in various forms of brain cancer. 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 AT/RT in June 2022.

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.

## **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," "intend," "potential," "prospective," 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. Such statements are based on Kazia's expectations and projections about future events and future trends affecting our 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 trials and product development and 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 to 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. Actual results could differ materially from those discussed in this announcement.

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