ASX RELEASE
30 June 2022

KAZIA PROVIDES PROGRESS UPDATE ON PAXALISIB AND EVT801 CLINICAL PROGRAMS

Sydney, 30 June 2022 – Kazia Therapeutics Limited (NASDAQ: KZIA; ASX: KZA), an oncology-focused drug development company, is pleased to provide an update on recent progress with its two pipeline assets, paxalisib and EVT801, and on recent corporate financing activity.

Key Points

- EVT801 phase I study protocol has cleared third dose level and is recruiting well.
- GBM AGILE pivotal study has opened in France, the fourth country to commence recruitment to the paxalisib arm.
- Phase I study of paxalisib in combination with radiotherapy for treatment of brain metastases at Memorial Sloan Kettering Cancer Center has been accepted for presentation at an upcoming academic conference in Q3 CY2022.
- ATM financing facility has realized gross proceeds of US$ 2,956,036 for the period ending June 2022, at an average price of $6.08 (approximately AU$ 0.88 per share).

Kazia CEO, Dr James Garner, commented, “Despite a challenging first half equity market for biotech companies, Kazia has continued to make good progress. The GBM AGILE pivotal study is progressing well, and appears on track for data in 2H CY2023, as anticipated. We have been pleased in the first half to see new data presented and milestones delivered from several projects, and we expect that pace to continue and increase during the second half.”

EVT801 Phase I Study

The phase I study of EVT801 in patients with advanced cancer continues to recruit well. The drug has recently completed the third of a potential eight dose levels and is anticipated to open recruitment to the fourth dose cohort in the near future. To date, the drug appears generally well-tolerated. Depending on how many dose cohorts are required to establish a maximum tolerated dose (MTD), interim data from the study is anticipated in 2H CY2022 or 1H CY2023.

GBM AGILE

More than forty sites are currently open to the paxalisib arm of GBM AGILE. The first site to commence recruitment to the paxalisib arm in France opened in June 2022, making France the fourth country to join the study, alongside the United States, Canada, and Switzerland.

In January 2022, the Global Coalition for Adaptive Research (GCAR), the sponsor of GBM AGILE, stated that over a thousand patients had been screened to the study, with enrolment rates approximating 0.75 to 1.00 patients per site per month, which is around four times higher than would generally be expected in a clinical study of glioblastoma.

Kazia continues to work closely with GCAR and Simcere Pharmaceutical to open the study in China. Public health measures in some Chinese cities relating to the ongoing COVID pandemic have had a modest impact on operational activities, but it is currently anticipated that the study will open in China during 3Q CY2022.

Paxalisib in Brain Metastases

In June 2022, the company announced that a multi-drug, genomically-guided study in brain metastases run by the Alliance for Clinical Trials in Oncology had seen the paxalisib arm graduate to an expansion cohort in patients with breast cancer brain metastases, having seen positive efficacy signals in the initial exploratory cohort. Paxalisib continues to recruit to the exploratory cohort in two other patient subgroups.

Interim data from a phase I study of paxalisib in combination with radiotherapy for patients with brain metastases run by Memorial Sloan Kettering Cancer Center has been accepted for an oral presentation at an upcoming international conference in Q3 CY2022. Kazia looks forward to sharing data from this presentation as soon as it is available.

Financing

In May 2022, Kazia established a NASDAQ-based at-the-market financing facility with Oppenheimer and Company. For the period ending June 30, 2022, the company has issued 486,281 American Depository Shares (ADSs) under this facility, at an average price of $6.08, for total gross proceeds of US$ 2,956,036 (approximately AU$ 4,256,691). Of note, these shares have been issued at no discount, with no warrant coverage, and with transaction fees approximately half of those associated with traditional financing.

For More Information, Please Contact:-

In the United States:

Joe Green
Edison Investor Relations
jgreen@edisongroup.com
Phone: +1 646-653-7030

In Australia:

Jane Lowe
IR Department
jane.lowe@irdepartment.com.au
Phone: +61 411 117 774

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 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 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,” “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.