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KAZIA PROVIDES PROGRESS UPDATE ON PAXALISIB AND EVT801 CLINICAL PROGRAMS

Sydney, 30 June 2021 – 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.

Key Points

- GBM AGILE pivotal study of paxalisib is recruiting ahead of expectations, with almost 25 sites now open to the paxalisib arm.
- Paxalisib phase II study in newly diagnosed glioblastoma has seen the final patient complete drug treatment; a number of patients remain in follow-up.
- EVT801 phase I study protocol has been submitted to the French regulatory agency for review.

Kazia CEO, Dr James Garner, commented, "Kazia has seen an exceptionally busy first half, with excellent progress across our clinical programs. In particular, the GBM AGILE study is performing ahead of our forecasts in terms of recruitment. As we move into the second half of the year, we anticipate conclusion of the paxalisib phase II study, initial data readouts from a number of the paxalisib investigator-initiated studies in other forms of brain cancer, and commencement of the first-in-human phase I study of EVT801."

GBM AGILE

Almost twenty-five sites are currently open to the paxalisib arm in the United States. The list includes prestigious centres such as Memorial Sloan Kettering Cancer Center, Henry Ford Cancer Institute, Columbia University Irving Cancer Research Center, Emory University Winship Cancer Institute, and the University of Florida. The first site in Canada is expected to open in August 2021, followed by the first European sites in Q4 CY2021.

To date, GBM AGILE has screened over 650 patients. This progress is expected to accelerate as new sites in new territories come on stream.

GBM AGILE is an international platform study design to identify effective therapies for glioblastoma. It is an adaptive study, that evaluates multiple therapies in parallel, and recruits only the number of patients needed in each arm to reach a definitive answer. With its innovative design and efficient operational infrastructure, GBM AGILE is faster and more cost-effective than conventional company-sponsored approaches, and data from GBM AGILE may be used as the foundation of a new drug application to FDA and other regulatory agencies. GBM AGILE has been designed and implemented by the Global Coalition for Adaptive Research, a world-leading consortium focused on adaptive clinical trials.

To date, three experimental therapies have joined GBM AGILE: Bayer's regorafenib, Kazia's paxalisib, and Kintara Therapeutics' VAL-083. It is expected that paxalisib will recruit up to 200 patients in the study, with the actual number determined by emergent data from the study.

Kazia has brought forward the manufacture of an additional batch of paxalisib investigational product, and this is expected to be released for use in the study during early 4Q CY2021.

Paxalisib Phase II Study

The final patient in the paxalisib phase II study has experienced disease progression after approximately 2.3 years on treatment. A number of patients remain in follow-up and the study is expected to conclude in 2H CY2021. Kazia anticipates no further interim analyses at this stage, and instead expects to release final data once the necessary analyses are complete.

Paxalisib Investigator-Initiated Studies

Kazia has been advised of generally good progress across the ongoing investigator-initiated studies of paxalisib in other forms of brain cancer. As previously indicated, the company expects that the respective investigators will release initial data from several of these studies during CY2021.

EVT801 Phase I Study

The study protocol for a planned phase I study of EVT801 has been submitted to ANSM, the French regulatory agency. Kazia expects to receive feedback from the agency late in 3Q CY2021.

The initial batch of EVT801 investigational product has been manufactured and is ready for use. Two leading academic research hospitals in France have been selected as the initial trial sites, with the potential to expand to additional sites as the study progresses.

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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 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. Eight 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.

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 is expected to begin in CY2021.

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

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