ASX RELEASE
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PHASE II STUDY OF PAXALISIB IN BRAIN METASTASES ADVANCES TO EXPANSION STAGE IN BREAST CANCER BRAIN METASTASES COHORT

Sydney, 7 June 2022 – Kazia Therapeutics Limited (NASDAQ: KZIA; ASX: KZA), an oncology-focused drug development company, is pleased to announce that a phase II, genomically-guided study of multiple therapies in patients with brain metastases, led by the Alliance for Clinical Trials in Oncology (NCT03994796), has advanced the paxalisib arm to an expansion stage in breast cancer, following completion of the pre-specified interim analysis.

Key Points

- The Alliance study, also known as A071701, commenced enrolment in 2019. The study is recruiting patients with brain metastases (cancer that has spread to the brain from elsewhere in the body) from breast cancer, lung cancer, or other primary tumors. Patients are assigned to receive either abemaciclib (Lilly), entrectinib (Genentech), or paxalisib (Kazia), depending on the genetic profile of their tumor.
- The study is sponsored by the Alliance for Clinical Trials in Oncology, a U.S.-based cancer research network sponsored by the National Cancer Institute. Kazia has supported the study with a financial grant, and with provision of paxalisib study drug.
- For each drug – tumor combination (e.g., paxalisib in patients with lung cancer brain metastases), the study envisages an initial stage of ten patients for each subgroup (*i.e.*, breast, lung, other). If the pre-specified response criteria are met at the interim analysis of ten patients per subgroup, the study expands that drug-tumor combination to enroll eleven additional patients, in order to seek definitive efficacy data.
- The paxalisib arm has fully recruited the breast cancer cohort for the initial pre-specified interim analysis and has met the threshold for transition to the expansion stage of the study.
- The initial stage of the study remains ongoing for paxalisib in lung cancer and in other tumors.

"Brain metastases are a complication of several common cancers, and effective treatments remain elusive," said Priscilla Brastianos, MD, Principal Investigator of the study, and Associate Professor of Medicine at Harvard Medical School. "This study has been designed to identify potential new therapies for patients with brain metastases, using leading genomic techniques to assign patients to the most appropriate treatment. We are looking forward to continuing our exploration of paxalisib in this important disease area."

Brain Metastases

Up to 30% of patients with metastatic cancer will develop secondary tumors (metastases) in the brain, and it is estimated that there are approximately 200,000 new cases of brain metastases each year in the United States alone. Treatment options remain limited, and average survival of patients with brain metastases ranges from 3 to 27 months, depending on factors such as the location of the original tumor.

It is increasingly recognized that cancer is a complex disease, in which tumors in a similar location (*e.g.*, breast, lung) may respond very differently to treatment. An important factor in this is the genetic profile of the tumor. Clinical studies have begun to focus on carefully allocating patients to treatment on basis of this genetic profile, an approach which is sometimes referred to as 'precision medicine' or 'personalized medicine'. The Alliance study is an example of this approach.

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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. 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.

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.

About the Alliance for Clinical Trials in Oncology

The Alliance for Clinical Trials in Oncology (Alliance) is a clinical trials network that involves approximately 10,000 physicians across the United States and Canada. The Alliance seeks to reduce the impact of cancer on people by uniting a broad community of scientists and clinicians from many disciplines, committed to discovering, validating and disseminating effective strategies for the prevention and treatment of cancer. It is part of the National Clinical Trials Network (NCTN) sponsored by the National Cancer Institute (NCI). For more information about the Alliance, please visit www.AllianceforClinicalTrialsinOncology.org.

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.