

ASX RELEASE

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KAZIA ENTERS CLINICAL COLLABORATION FOR METASTATIC BRAIN CANCER WITH ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

Sydney, 20 May 2019 – Kazia Therapeutics Limited (ASX: KZA; NASDAQ: KZIA), an Australian oncology-focused biotechnology company, is pleased to announce that it has entered into a collaboration with the Alliance for Clinical Trials in Oncology Foundation (Alliance), a US-based cancer research network sponsored by the National Cancer Institute. Alliance will launch a multi-centre phase II study to investigate the potential use of Kazia’s investigational new drug, GDC-0084, alongside several other targeted cancer therapies, in the treatment of brain metastases (cancer that has spread to the brain).

“Brain metastases truly represent an unmet clinical need,” said Priscilla Brastianos, MD, Principal Investigator of the study, and Assistant Professor of Medicine at Harvard Medical School. “We urgently need to find better treatment options for these patients. We hope this study will help us identify a new treatment paradigm.” Dr Brastianos is also an Assistant Physician in Medicine in the Department of Hematology/Oncology at Massachusetts General Hospital. Her research interests focus on metastatic brain cancer, and she has been extensively published in this field. Dr Brastianos will be joined on the study Steering Committee by distinguished expert clinicians from leading centres across the United States.

Key Points

- Alliance will initiate an open-label phase II study in patients with brain metastases.
- Depending on the genetic profile of their tumor, patients will be allocated to receive either abemaciclib (Eli Lilly), entrectinib (Genentech), or GDC-0084 (Kazia Therapeutics).
- The trial is expected to recruit up to 150 patients in multiple centers across the US.
- The trial will be led by Alliance, with Kazia providing support including study drug and a financial grant.
- Initiation of this study brings the total number of ongoing clinical trials with GDC-0084 to four, each in different forms of brain cancer.

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

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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.

The Alliance study, also known as A071701, is expected to recruit up to 150 patients in total, all of whom will have cancer that has spread to the brain. Only patients with a genetic alteration in the PI3K pathway will receive GDC-0084, and it is expected that approximately one third of the total patients will be in this group. Patients with other genetic mutations will be allocated to receive either abemaciclib, a CDK inhibitor, also known as Verzenio™, that is manufactured by Eli Lilly and has been approved by FDA for the treatment of certain forms of breast cancer, or entrectinib, a Trk/ALK inhibitor manufactured by Genentech, which has not yet been approved by FDA.

Dr James Garner, Chief Executive Officer of Kazia Therapeutics commented, "The Alliance study is a ground-breaking research project that aims to investigate several experimental drugs in a single clinical study. Patients will be allocated to treatment depending on their tumor's individual genetic signature, and patients with a mutation affecting the PI3K pathway will be eligible to receive GDC-0084. This kind of approach is very much the future of cancer treatment. We are delighted that GDC-0084 has been selected and we are excited to see this study move forward."

The initiation of the study brings to four the number of ongoing clinical trials with GDC-0084:

Sponsor	Phase	Indication	Registration
Kazia Therapeutics	II	Glioblastoma	NCT03522298
Dana-Farber Cancer Institute	II	Breast cancer brain metastases (with Herceptin®)	NCT03765983
Alliance for Clinical Trials in Oncology	II	Brain metastases	(TBA)
St Jude Children's Research Hospital	I	DIPG (childhood brain cancer)	NCT03696355

It is expected that the study will take approximately two years to complete. Kazia will provide support, including a financial grant to defray a portion of the costs. The study will be conducted under an 'investigator IND' with the US FDA, in which the primary regulatory responsibilities for the study will be assumed by Alliance. Implementation of the study is conditional upon approval from applicable Institutional Review Boards, and completion of contractual formalities, and these matters have not yet been finalised. It is expected that the study will begin recruitment in the second half of calendar 2019.

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About Kazia Therapeutics Limited

Kazia Therapeutics Limited (ASX: KZA, NASDAQ: KZIA) is an innovative oncology-focused biotechnology company, based in Sydney, Australia. Our pipeline includes two clinical-stage drug development candidates, and we are working to develop therapies across a range of oncology indications.

Our lead program is GDC-0084, a small molecule inhibitor of the PI3K / AKT / mTOR pathway, which is being developed to treat glioblastoma multiforme, the most common and most aggressive form of primary brain cancer in adults. Licensed from Genentech in late 2016, GDC0084 entered a phase II clinical trial in 2018. Initial safety data was released in May 2019, and efficacy data is expected in 2H 2019. GDC-0084 was granted orphan designation for glioblastoma by the US FDA in February 2018.

TRX-E-002-1 (Cantrixil), is a third-generation benzopyran molecule with activity against cancer stem cells, and is being developed to treat ovarian cancer. TRX-E-002-1 is currently undergoing a phase I clinical trial in Australia and the United States. Initial data was presented at the AACR annual conference in April 2019 and the study remains ongoing. Cantrixil was granted orphan designation for ovarian cancer by the US FDA in April 2015.

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 US National Cancer Institute (NCI).