ASX RELEASE

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KAZIA TO TEST GDC-0084 WITH RADIOTHERAPY IN PHASE I CLINICAL TRIAL AT LEADING US CANCER CENTER

Sydney, 22 July 2019 – Kazia Therapeutics Limited (ASX: KZA; NASDAQ: KZIA), an Australian oncology-focused biotechnology company, is pleased to announce that Memorial Sloan Kettering Cancer Center (MSK) in New York, NY will investigate the potential use of Kazia's investigational new drug, GDC-0084, in combination with radiotherapy in a phase I clinical trial for cancer that has spread to the brain (brain metastases and leptomeningeal metastases). This research will explore a new use of GDC-0084 and will run concurrently with other ongoing studies in different forms of brain cancer.

Dr James Garner, Chief Executive Officer of Kazia Therapeutics commented, "MSK is one of the world's leading cancer treatment centers, and we are privileged to be supporting them in this state-of-the-art project. Many cancers have the potential to spread to the brain, and they become very difficult to treat when they do. The work being done at MSK will investigate whether GDC-0084 has the potential to enhance the effects of radiotherapy, which remains the current standard of care in most cases."

Key Points

- MSK will initiate a phase I clinical trial of GDC-0084 in combination with radiotherapy for patients with solid tumor brain metastases (cancer that has spread to the brain) and leptomeningeal metastases that harbors a genetic alteration in the PI3K pathway.
- The trial is expected to recruit 18-30 patients and will take about two years to complete.
- The trial will be led by MSK, with Kazia providing support including study drug and a financial grant.
- Initiation of this study brings to five the total number of ongoing clinical trials with GDC-0084, each in different forms of brain cancer.

Up to 30% of patients with metastatic cancer will develop secondary tumors (metastases) in the brain. Radiotherapy remains the standard of care, but 30-50% of patients will progress within one year, despite best available treatment. In animal models of certain cancers, activation of the PI3K pathway has been shown to contribute to radiotherapy resistance. GDC-0084 is a PI3K inhibitor that can cross the blood-brain barrier, and as such it may be able to

reduce the problem of resistance to radiotherapy. This clinical trial has been developed to test that hypothesis.

The trial is expected to recruit 18-30 patients, all of whom will have cancer that has spread to the brain. Patients will be genetically tested for a specific alteration in the PI3K pathway, and only those with a relevant mutation will be enrolled. This is an example of an approach to clinical research that is sometimes referred to as 'precision medicine' or 'personalized medicine', in which treatments are carefully targeted to those patients most likely to benefit. It is expected that the trial will begin recruitment in the second half of calendar 2019.

The study in two parts. The first part will aim to determine the maximum tolerated dose (MTD) of GDC-0084 when given together with radiotherapy. Once that dose has been determined, the second part of the study will enroll an additional twelve patients at that dose to explore preliminary signals of efficacy.

The Principal Investigator for the study is Dr T Jonathan Yang, Director of Metastatic Disease Program in MSK's Department of Radiation Oncology. Dr Yang is a graduate of Yale University School of Medicine and a Board-certified radiation oncologist, with a specialist interest in treating tumors of the central nervous system. He is an extensively-published clinical researcher who has participated in a substantial number of clinical trials in brain cancer.

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

Sponsor	**Phase**	**Indication**	**Registration**
Kazia Therapeutics	II	Glioblastoma	NCT03522298
Alliance for Clinical Trials in Oncology	II	Brain metastases	NCT03994796
Dana-Farber Cancer Institute	II	Breast cancer brain metastases (*with Herceptin*)	NCT03765983
St Jude Children's Research Hospital	I	DIPG (childhood brain cancer)	NCT03696355
Memorial Sloan Kettering Cancer Center	I	Brain metastases (*with radiotherapy*)	(TBA)

It is expected that the study will take approximately two years to complete. Kazia will provide support, including a financial grant for 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 MSK. Implementation of the study is conditional upon approval from the Institutional Review Board at MSK, and this approval has yet to be obtained.

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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.