ASX RELEASE

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KAZIA ENTERS CLINICAL COLLABORATION WITH DANA-FARBER CANCER INSTITUTE

Sydney, 22 October 2018 – 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 Dana-Farber Cancer Institute (DFCI) in the United States, to investigate the potential use of Kazia's investigational new drug, GDC-0084, in breast cancer that has spread to the brain, a potential new indication for the drug.

Key Points

- DFCI will initiate an open-label phase II clinical trial of GDC-0084 in combination with Herceptin (trastuzumab) in patients with HER2-positive breast cancer that has metastasised to the brain
- Study estimated to recruit between 22 and 49 patients, and will take up to three years to complete
- Kazia will provide support including study drug and a financial grant
- DFCI study will run in parallel with Kazia's ongoing phase II clinical trial of GDC-0084 in adults with newly-diagnosed glioblastoma multiforme (GBM)

Dana-Farber Cancer Institute (DFCI) is a world-leading cancer treatment and research centre, based in Boston, Massachusetts. It is a principal teaching affiliate of Harvard Medical School, and has been designated a Comprehensive Cancer Center by the US National Cancer Institute. DFCI participates in as many as 600 clinical trials at any given time, and has been an important contributor to the development and approval of a number of important new cancer therapies.

Approximately 20-30% of early-stage breast cancers are described as 'HER2-positive', and these patients are generally treated with Herceptin (trastuzumab), which was invented by Genentech and approved by FDA in 1998.

The efficacy of Herceptin is well established. However, breast cancer can spread to other parts of the body, a process described as metastasis, and in up to half of these cases the brain is the site to which it spreads. Such breast cancer brain metastases (BCBM) are often highly resistant to Herceptin, in contrast to the original tumour, and there remains a substantial need for new therapies in this patient population.

Recent research had suggested that the PI3K pathway may represent an important part of this resistance mechanism, and so there is a sound rationale to explore GDC-0084, a brain-

penetrant PI3K inhibitor, as a potential treatment for patients with breast cancer that has metastasized to the brain.

Kazia CEO, Dr James Garner, commented, "we strongly believe in the potential for GDC-0084 to bring benefit to patients with other forms of brain cancer beyond glioblastoma, and it is exciting to be working with the team at Dana-Farber to explore its potential use in this very challenging disease. It is extremely gratifying to be able to work with specialist researchers of this calibre, at a centre held in such high regard, and we are committed to seeing this important study move forward."

It is estimated that the DFCI study will recruit up to 49 patients with brain metastases from HER2-positive breast cancer. The core of the study (Cohort A) will seek preliminary evidence of efficacy for GDC-0084 in patients with brain metastases. It will be an open-label, single-arm study. 12 patients will initially be enrolled, and if there is evidence of response then an additional 25 patients will be recruited. An exploratory cohort (Cohort B) will investigate the response of certain biomarkers to GDC-0084 treatment using tissue samples obtained from surgical resection, and is expected to recruit 10-12 patients.

The Principal Investigator for the study is Dr Jose Pablo Leone, a medical oncologist at DFCI with a specialist focus on breast cancer. In addition, the study will be overseen by Dr Nancy Lin, an Associate Professor of Medicine at Harvard Medical School and Head of the Metastatic Breast Cancer Program at DFCI. Both Dr Leone and Dr Lin are extensively-published researchers in BCBM.

The study is expected to take approximately three years to complete. Kazia will provide support, including a financial grant to cover 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 DFCI. Implementation of the study is conditional upon approval from the Institutional Review Board at DFCI, and this approval has not yet been obtained. It is expected that the study will begin recruitment in late calendar 2018 or early calendar 2019.

DFCI will also be a participant in Kazia's phase II clinical trial of GDC-0084 in glioblastoma, but the two projects will run separately, with the glioblastoma study proceeding under Kazia's sponsorship and the breast metastases study under the sponsorship of DFCI.

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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, GDC-0084 entered a phase II clinical trial in March 2018. Initial data is expected in early calendar 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 in June 2018 and the study remains ongoing. Cantrixil was granted orphan designation for ovarian cancer by the US FDA in April 2015.