

ASX RELEASE

6 May 2019

KAZIA ANNOUNCES SUPERIOR SAFETY AND TOLERABILITY DATA FROM PHASE IIA STUDY OF GDC-0084 IN NEWLY-DIAGNOSED GLIOBLASTOMA PATIENTS

***Dose Expansion Cohort to Begin Recruitment Immediately;
Top-line Data Expected in 4Q Calendar 2019***

Sydney, 6 May 2019 – Kazia Therapeutics Limited (ASX: KZA; NASDAQ: KZIA), an Australian oncology-focused biotechnology company, is pleased to announce new safety data from its ongoing phase IIA study of GDC-0084 in newly-diagnosed patients with glioblastoma (GBM).

Licensed from Genentech in October 2016, GDC-0084 is a novel targeted therapy that inhibits the PI3K pathway, which is important in many forms of cancer and is activated in 85-90% of GBM cases. GDC-0084 is administered orally, once daily.

The phase IIA study has determined a maximum tolerated dose (MTD) of 60mg, which is substantially higher than the 45mg dose found during Genentech's phase I study in patients with recurrent disease. Dose-limiting toxicities in this phase IIA study included oral mucositis (mouth ulcers) and hyperglycemia (elevated blood sugar), both of which are expected effects of the PI3K inhibitor class of drugs.

Dr James Garner, Chief Executive Officer of Kazia Therapeutics commented, "this is an important milestone, and we are very encouraged by these results. Genentech's original phase I study examined GDC-0084 in very advanced patients, who are often less able to tolerate therapy. They reached an MTD of 45mg, which is expected to be within the therapeutic range. When we licensed the drug from Genentech, we recognized the opportunity to refocus around newly-diagnosed patients, who are often in generally better health. The fact that the drug appears better tolerated here than in the previous study validates our strategy for GDC-0084, and bodes well for the clinical efficacy of the drug."

Kazia's phase IIA study of GDC-0084 is designed in two parts. The first part, which began dosing in September 2018 and is now complete, is a dose optimization component, designed to determine if newly-diagnosed patients could tolerate a higher dose of GDC-0084 than advanced recurrent patients. This part of the trial was expected to enroll between 6 and 18 patients, depending on the safety signal observed. Ultimately, a total of eight patients were

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Mr Iain Ross Chairman, Non-Executive Director

Mr Bryce Carmine Non-Executive Director

Mr Steven Coffey Non-Executive Director

Dr James Garner Chief Executive Officer, Managing Director

required for this part. The study will now immediately transition into the dose expansion cohort, in which an additional 20 patients will be recruited. It is planned that these patients will receive a dose of 60mg. This second part of the study will be designed to provide confirmatory efficacy signals, and is expected to report initial data in the fourth quarter of calendar 2019.

In total, seven sites in the United States are currently participating:-

Site	Principal Investigator
Dana Farber Cancer Institute, Boston, MA	Prof. Patrick Wen
MD Anderson Cancer Center, Houston, TX	Prof. John de Groot
John Theurer Cancer Center, Hackensack, NJ	Dr. Samuel Goldlust
Massachusetts General Hospital, Boston, MA	Dr. Elizabeth Gerstner
Stephenson Cancer Center, Oklahoma City, OK	Asst. Prof. James Battiste
University of California Los Angeles, Los Angeles, CA	Prof. Tim Cloughesy
University of Colorado Cancer Center, Aurora, CO	Asst. Prof. Denise Damek

The study is registered on clinicaltrials.gov as NCT03522298.

Dr Garner added, “the total clinical experience with GDC-0084 is now approaching 70 patients. The side effects that we have seen to date have all been very typical for this type of drug: mouth ulcers, high blood sugar, etc. Critically, we have not seen any of the more serious side effects that have sometimes been observed with other drugs in the class, such as infections, liver toxicity, or gastrointestinal problems. This is very reassuring as we prepare to take the drug forward into the next phase of development.”

[ENDS]

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. Preliminary efficacy data is expected in 4Q 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.