ASX RELEASE

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PROGRESS UPDATE ON GDC-0084 PROGRAM

Sydney, 29 October 2018 – Kazia Therapeutics Limited (ASX: KZA; NASDAQ: KZIA), an Australian oncology-focused biotechnology company, is pleased to provide an update to shareholders regarding progress with GDC-0084, which is currently in human trials for glioblastoma and several other forms of brain cancer.

Key Points

- Phase II clinical trial of GDC-0084 in glioblastoma is progressing well, with all sites open to recruitment and the first cohort of patients fully enrolled and undergoing treatment
- Investigator-initiated clinical collaborations launched with St Jude Children's Research Hospital in diffuse intrinsic pontine glioma (DIPG), and with Dana-Farber Cancer Institute in breast cancer brain metastases (BCBM)
- Poster on the Kazia glioblastoma study to be presented at upcoming Society for Neuro-Oncology meeting in New Orleans, LA on 16 November 2018
- Manufacture of an additional batch of GDC-0084 capsules for clinical trial use has commenced

Kazia CEO, Dr James Garner, commented "we are delighted with progress across the GDC-0084 program. Our own study in glioblastoma is off to an excellent start, and we are very pleased to now also be working with two top-tier research hospitals to explore additional uses of the drug in other forms of brain cancer. The hard work that has been undertaken over the past twelve to eighteen months is now paying off, which sets the company up for several important and value-driving data read-outs from the GDC-0084 program during calendar 2019."

He added, "the PI3K inhibitor class has seen some dramatic developments in the past six months. We were excited to see FDA approve Copiktra (duvelisib) from Verastem in October 2018, bringing the number of FDA-approved PI3K inhibitors to three. The recent European Society for Medical Oncology (ESMO) meeting also saw promising data presented from Novartis for their PI3K inhibitor, alpelisib, in certain forms of breast cancer. It is clear that this class of drugs is well-established and well-proven. However, GDC-0084 remains the only PI3K inhibitor in mainstream development that is able to cross the blood-brain barrier, and this gives it a unique advantage in brain cancer."

Phase II Clinical Trial in Glioblastoma

All seven participating centres are fully open to recruitment. To date, the first cohort of three patients has been enrolled and are currently receiving treatment. If the first cohort is able to complete treatment without experiencing significant toxicity, a second cohort will be enrolled at a higher dose. A number of potential patients have already been identified for the second cohort and are undergoing pre-screening. Once the maximum tolerated dose (MTD) has been established in this first part of the trial, the remainder of the study will proceed at that dose.

Recruitment to date has exceeded expectations, and the study remains on track to report initial data early in calendar 2019. It is listed on clinicaltrials.gov as NCT03522298. The study is also listed in the clinical trial finder section of the US National Brain Tumor Society website.

Investigator-Initiated Collaborations

As previously announced, Kazia is supporting two leading US hospitals to explore the potential use of GDC-0084 in other forms of brain cancer.

St Jude Children's Research Hospital in Memphis, TN has commenced a phase I human trial of GDC-0084 in children with diffuse intrinsic pontine glioma (DIPG) and other diffuse midline gliomas. This study is currently recruiting and is listed on clinicaltrials.gov as NCT03696355.

Dana-Farber Cancer Institute (DFCI) in Boston, MA is establishing a phase II human trial of GDC-0084 in women with breast cancer brain metastases (BCBM), which is breast cancer that has spread to the brain. This study is expected to commence recruitment in early calendar 2019, pending approval by the Institutional Review Board at DFCI, and is not yet listed on clinicaltrials.gov.

Kazia has been pleased to observe very strong interest from clinicians and scientists in a range of other potential exploratory studies of GDC-0084 and remains in discussion regarding several other potential clinical collaborations.

Publications

Kazia is gratified to have been accepted for a 'trials in progress' poster presentation at the upcoming 23rd Annual Scientific Meeting of the Society for Neuro-Oncology (SNO), which will be held in New Orleans, LA on 16-18 November 2018.

The Company will make the poster presentation available to all shareholders at approximately the same time it is presented at conference. The poster is expected to focus primarily on the design of the company-sponsored ongoing phase II study in glioblastoma, and the rationale for GDC-0084 in this group of patients, and it is not anticipated that meaningful clinical data will be available at this early stage.

Other presentations and publications of GDC-0084 data are anticipated in the next six to twelve months, and the Kazia team will be discussing appropriate opportunities with investigators at the upcoming SNO meeting.

Manufacturing

Work has begun to manufacture a second batch of capsules for use across the GDC-0084 clinical program, under international Good Manufacturing Practice (GMP) conditions. The company obtained approximately 48kg of drug substance as part of its transaction with Genentech in October 2016, and this remains highly stable. Kazia has planned to periodically formulate a portion of this material into capsules for clinical trial use, according to progress with the studies. Given the pace of recruitment to date, it has been considered appropriate to accelerate manufacture of a second batch of capsules to ensure continuity of supply. Production of a second batch will also strengthen the data available regarding GDC-0084 manufacture for regulatory purposes, and will ultimately help to inform commercial supply.

Regulatory Affairs

In accordance with FDA requirements, Kazia has been undertaking a 13-week toxicology study of GDC-0084 in two animal species. This is a routine requirement to support long-term use of the drug in human patients. The study is progressing well according to plans, and is on track to conclude before the end of calendar 2018.

Kazia has applied to the World Health Organisation (WHO) for an International Non-proprietary Name (INN) for GDC-0084. It is common for drugs to be referred to by a code number during early development, but companies typically seek allocation of an INN around the initiation of phase II development. INNs are a necessary step for eventual regulatory approval and are determined centrally by WHO. Kazia expects to receive the INN for GDC-0084 in late calendar 2019.

Intellectual Property

Since assuming responsibility for GDC-0084 from Genentech in October 2016, Kazia has continued to pursue robust protection for the intellectual property associated with the drug. Of note, patents have been granted in Australia (July 2017), the People's Republic of China (March 2018), Hong Kong SAR (March 2017), and the United States (January 2017), as well as in a number of other jurisdictions. In general, the patents relating to GDC-0084 provide comprehensive protection until at least 2031.

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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.