ASX RELEASE
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COMMENCEMENT OF PHASE II CLINICAL STUDY OF GDC-0084

Sydney, 29 March 2018 – Kazia Therapeutics Limited (ASX: KZA; NASDAQ: KZIA), an Australian oncology drug development company, is pleased to announce commencement of an international phase II clinical trial of its lead program, GDC-0084.

Key Points

- First site, Stephenson Cancer Center at the University of Oklahoma, has been initiated and will begin screening patients after the Easter holidays
- Study commencement follows a successful meeting with US Food & Drug Administration (FDA) in September 2017, and approval by Western Institutional Review Board in November 2017
- Initial focus will be on dose optimization in the treatment of newly-diagnosed patients with glioblastoma multiforme; adaptive study design will then seek to provide definitive evidence of clinical efficacy

GDC-0084 is being developed for glioblastoma multiforme (GBM), the most common and most aggressive form of primary brain cancer. The mainstay of current pharmacological treatment, temozolomide, is effective only in about one third of patients, and median survival is approximately 12 to 15 months from diagnosis.

Kazia licensed GDC-0084 in late 2016 from Genentech, a member of the Roche Group, where it had previously completed a phase I clinical study in 47 patients with advanced glioma. Genentech's phase I study demonstrated a favourable safety profile and provided signals of efficacy. Genentech also conducted an extensive preclinical program which showed encouraging results for GDC-0084 in animal models of glioblastoma.

Kazia CEO, Dr James Garner, commented, "the entire team has been working hard to design and implement the GDC-0084 clinical study. We are very pleased to now have the trial underway, and look forward to working with the participating clinicians. The need for new therapies in this disease remains immense, and we believe that GDC-0084 may have a valuable role to play in improving outcomes for patients with glioblastoma."

Board of Directors
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

This phase II study will initially be conducted predominantly at leading US-based centres, in collaboration with specialist clinicians in the neuro-oncology field, and under an Investigational New Drug (IND) filing with the US Food and Drug Administration. The study is awaiting registration with clinicaltrials.gov, and will commence screening patients after the Easter holidays. Not all patients will qualify, and some may withdraw during the initial phase of the study. It is anticipated that the study will provide an initial data read-out in early calendar 2019.

A video interview of Dr James Garner discussing the clinical study can be accessed via the Kazia corporate website at https://www.kaziatherapeutics.com/mediacentre/insight/why-gdc-0084-for-glioblastoma-qa-with-kazia-ceo-dr-james-garner. The Company has also prepared an animation to explain the activity of GDC-0084, and this can be accessed via the Kazia corporate website at https://www.kaziatherapeutics.com/mediacentre/insight/gdc-0084-and-glioblastoma-multiforme.

Commencement of the trial follows the decision of the US FDA to grant orphan drug designation to GDC-0084 in glioblastoma in February 2018. Since in-licensing the program, Kazia has been working closely with clinicians and advisors to build a comprehensive development program which aims to move GDC-0084 towards a product registration in the swiftest and most effective way. To date, this has included extensive regulatory consultation, manufacture of drug product for use in the phase II clinical trial, optimization of the intellectual property portfolio, and implementation of additional animal studies to support the further development of the drug.

Kazia Chairman, Iain Ross, commented, “this is an important achievement for the organisation. Two years ago, Kazia was an early-stage preclinical company. We now have two high-quality assets in clinical trials: Cantrixil in phase I for ovarian cancer and GDC-0084 in phase II for glioblastoma. The Board and Management have completed a significant transformation of the organization so as to optimally support this clinical-stage portfolio, and we are now a lean, cost-effective, and highly-focused biotech.”

He added, “we continue to be pleased with progress on the phase I study of Cantrixil, and look forward to reporting initial data from this study, which we expect will occur in the second calendar quarter of 2018.”

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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. 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.

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 is expected in the second quarter of calendar 2018.

For more information, please visit www.kaziatherapeutics.com