

ASX RELEASE

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KAZIA RECEIVES FDA ORPHAN DESIGNATION FOR GDC-0084

Sydney, 23 February 2018 – Kazia Therapeutics Limited (ASX: KZA; NASDAQ: KZIA), an Australian oncology-focused biotechnology company, is pleased to announce that the United States Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to Kazia's investigational new drug, GDC-0084, for the treatment of glioblastoma multiforme, the most common and most aggressive form of primary brain cancer. The company received written notification from FDA on Friday 23rd February 2018.

Key Points

- Orphan Drug Designation (ODD) is a special status accorded to drugs which are considered promising potential treatments for rare ('orphan') diseases, generally defined as those which affect less than 200,000 cases per annum in the United States
- ODD can provide drug developers with up to seven years of Orphan Drug Exclusivity (ODE), extending the effective life of a commercial product. It also provides opportunities for grant funding, protocol assistance, and financial benefits, such as a waiver of New Drug Application fees, and tax credits
- Licensed from Genentech in October 2016, GDC-0084 is due to commence a phase II clinical trial in glioblastoma in late March or early April of 2018

Glioblastoma multiforme (GBM) is an area of significant unmet medical need. More than 130,000 patients are diagnosed worldwide each year, and the prognosis remains poor, with median survival of 12-15 months on best available care. Existing drug treatments are largely ineffective in almost two-thirds of patients, and there remains an urgent need for new therapies.

GDC-0084 was licensed from Genentech in late 2016, after demonstrating favourable results in a phase I study of 47 patients with advanced brain cancer. Kazia intends to shortly commence an international phase II clinical study to provide definitive evidence of clinical efficacy. This phase II study will initially be conducted predominantly at leading centres in the United States, and is anticipated to provide an initial data read-out in early calendar 2019.

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

Kazia CEO, Dr James Garner, commented, “we are very pleased to have successfully completed this important regulatory step in the development of GDC-0084. We share FDA’s recognition of the need for new treatments in this very challenging disease, and we believe that GDC-0084 has great promise as a potential new therapy. We anticipate an imminent start of the phase II clinical study, and look forward to working closely with the participating clinicians.”

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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 is due to enter a phase II clinical trial in late March or early April of 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 first half of calendar 2018.

For more information, please visit www.kaziatherapeutics.com.