ASX RELEASE

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KAZIA COMPLETES RECRUITMENT OF CANTRIXIL PHASE I CLINICAL TRIAL

Sydney, 13 August 2019 – Kazia Therapeutics Limited (ASX: KZA; NASDAQ: KZIA), an Australian oncology-focused biotechnology company, is pleased to announce that it has completed recruitment of patients into Part B of its phase I clinical study of Cantrixil in ovarian cancer.

Dr James Garner, Chief Executive Officer of Kazia Therapeutics commented, "Part B of the Cantrixil study has recruited well and we are now following patients through to completion of their treatment. We are grateful for the excellent efforts of the participating clinicians, and of the study team. The first part of the study has shown some very promising signals, and the data from Part B will significantly enhance our understanding of the drug. We will be presenting data at the ESMO conference at the end of September, and this will be valuable opportunity to move forward our partnering discussions for Cantrixil."

Key Points

- Part A of the study collected data from an initial 14 patients, who received escalating doses of Cantrixil to determine safety and tolerability. A maximum tolerated dose of 5 mg/kg was achieved, and this data was reported at the American Association of Cancer Research conference on 1 April 2019.
- Part B was designed to enroll 12 patients, all of whom receive Cantrixil at a dose of 5 mg/kg. Part B was designed to seek preliminary signals of potential efficacy for the drug.
- Initial data from Part B is expected in the fourth quarter of calendar 2019, with final completion of the study in 2020.

Kazia was pleased to present positive data from the first part (Part A) of the study at the American Association of Cancer Research (AACR) on 1 April 2019. The data showed that, of nine patients evaluable for efficacy, five (56%) achieved a best observed response of stable disease after two cycles of Cantrixil monotherapy. One of these five patients subsequently achieved a partial response when Cantrixil was administered with chemotherapy. The study also determined a Maximum Tolerated Dose (MTD) of 5 mg/kg, which is the dose that is being used for all patients in Part B of the study.

Final data from these nine patients in Part A, including from the off-treatment follow-up period, has been selected for presentation at the European Society of Medical Oncology Annual Meeting in Barcelona, Spain on 27 September – 1 October 2020.

The phase I study of Cantrixil commenced in December 2016 and is registered on clinicaltrials.gov as NCT02903771. The study is being conducted at six hospitals in the United States and Australia:-

Site	**Principal Investigator**
United States	
Lifespan Cancer Institute, Providence, RI	Dr. Don Dizon
Stephenson Cancer Center, Oklahoma City , OK	Assoc. Prof. Kathleen Moore
Mary Crowley Cancer Research Centre, Dallas, TX	Dr. Minal Barve
Australia	
ICON Cancer Care, Brisbane, QLD	Assoc. Prof. Jermaine Coward
Westmead Hospital, Sydney, NSW	Prof. Paul Harnett
Flinders Medical Centre, Adelaide, SA	Dr. Ganessan Kichenadasse

Approximately 240,000 women are diagnosed with ovarian cancer each year worldwide and it is the eighth most common cause of cancer death in women. Conventional treatment typically includes surgery, radiotherapy, and chemotherapy. However, the five-year survival rate remains low, at approximately 45%, reflecting the fact that the disease is often advanced at the time of diagnosis.

[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, 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 2018. Initial safety data was released in May 2019, and efficacy data is expected in 2H 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.