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CANTRIXIL PHASE I STUDY PROGRESSES TO NEXT STAGE

Sydney, 10 October 2018 – Kazia Therapeutics Limited (ASX: KZA; NASDAQ: KZIA), an Australian oncology-focused biotechnology company, is pleased to announce the successful completion of Part A, the dose escalation component, of its phase I study of Cantrixil in ovarian cancer.

After discussion by the Data Monitoring Committee, the study has determined a maximum tolerated dose (MTD) of 5 mg/kg, and it is expected that this dose will be used for subsequent clinical investigation. Preclinical data suggests that this dose should be sufficient to detect potential therapeutic effects of Cantrixil.

The study will now move into Part B, a dose expansion cohort, which is designed to seek preliminary evidence of efficacy. Part B will recruit a further 12 patients, all of whom are expected to be dosed at the MTD of 5mg/kg. The company expects to be able to conclude Part B in calendar 2019.

Kazia CEO, Dr James Garner, commented, “we are delighted with progress in the Cantrixil study. The first hurdle for any drug in development is safety, and so it is highly encouraging that we have achieved in Part A of the trial a dose for Cantrixil towards the upper end of the range that we set out to explore. The study will now immediately transition into Part B, which will provide important insights into the potential efficacy of Cantrixil, building on the preliminary data that was announced in June 2018. We are grateful to the clinicians and patients who have driven the study forward so far, and we look forward to seeing further progress in due course.”

To date, 14 patients have been enrolled in the Cantrixil phase I study, all with ovarian cancer that has failed at least two prior lines of treatment and, of these, 11 have been well enough to receive treatment with Cantrixil. The most common side effects seen with Cantrixil administration have been abdominal pain, fatigue, and vomiting. Several patients continue to receive study drug at this time and as a result no further interim efficacy data is available at this point. The company is planning opportunities for publication of emerging safety and efficacy data with participating clinicians, and looks forward to sharing a comprehensive analysis in the near future, within the context of a suitable academic forum or publication.

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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.