ASX RELEASE

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NEW DATA FROM CANTRIXIL PHASE I STUDY IN OVARIAN CANCER PRESENTED AT ESMO CONFERENCE

Sydney, 30 September 2019 – Kazia Therapeutics Limited (ASX: KZA; NASDAQ: KZIA), an Australian oncology-focused biotechnology company, is pleased to provide investors with additional data from its ongoing phase I study of Cantrixil in ovarian cancer. The data will be the subject of a poster presentation at the annual Congress of the European Society for Medical Oncology (ESMO), held in Barcelona, Spain from 27 September – 1 October 2019.

The first part of the study (Part A) has demonstrated two out of nine patients (22%) with a best observed response of 'partial response' (PR). The median progression free survival (PFS) across all nine patients is 5.5 months, which compares favourably to historical controls of 3.4 months in a similar population.

Australian lead investigator for the study, Associate Professor Jim Coward, commented, "we have made excellent progress with the Cantrixil study. We are seeing several patients now with potential evidence of clinical response. Interestingly, some early signs are emerging that the drug may help to reverse chemotherapy resistance, supporting the preclinical data that was originally collected at Yale. The expansion cohort is fully recruited, and my colleagues and I look forward to seeing further data in due course."

Key Points

- ESMO poster includes additional data from all nine evaluable patients in the dose escalation part of the study (Part A). Some post-treatment follow-up data remains to be analysed.
- Of nine patients, two (22%) were considered to have achieved a 'partial response' (PR) to Cantrixil therapy. Three further patients (33%) were evaluated as 'stable disease' (SD). The remaining four patients (44%) exhibited 'progressive disease' (PD).
- The median progression free survival (PFS) for all patients in Part A was calculated to be 5.5 months. Historical controls in a similarly advanced population report a median PFS of 3.4 months, suggesting that Cantrixil may help to delay tumour recurrence.
- Cantrixil has been generally well-tolerated, with a maximum tolerated dose of 5 mg/kg determined, as previously announced.

Kazia CEO, Dr James Garner, added, "it is terrific to see further very promising data emerging from the Cantrixil phase I study. Put simply, the drug is active. The expansion cohort, which is currently in progress, will help us to further quantify and substantiate that activity. In parallel, we continue to discuss the program with clinicians, potential partners, and investors, as we consider how best to take Cantrixil forward after completion of the phase I study."

The poster can be viewed on our website at :
https://www.kaziatherapeutics.com/researchpipeline/cantrixil

Background

The phase I study of Cantrixil commenced in December 2016 and is registered on clinicaltrials.gov as NCT02903771. It is structured in two parts: Part A was primarily designed to understand the safety profile of Cantrixil and to establish the Maximum Tolerated Dose (MTD). The ESMO poster reports data from the nine evaluable patients recruited in Part A. The ESMO poster follows the presentation of interim data from the study at the AACR Annual Meeting in April 2019.

Part B has recruited 12 patients at the MTD to seek preliminary signals of efficacy. Recruitment to Part B was completed in August 2019, and Kazia expects to report data from this component of the study early in calendar 2020.

All patients had recurrent or persistent ovarian cancer and had failed at least two prior lines of therapy, including platinum therapy, prior to study entry, representing a very advanced population. After two cycles of treatment with Cantrixil, five of nine evaluable patients (56%) achieved stable disease (SD), according to the industry-standard RECIST criteria, which means that the tumour remained approximately the same size over time and had not progressed. Two of these patients (22%) subsequently achieved a partial response (PR) when Cantrixil was administered with standard-of-care chemotherapy, which means that the tumour was reduced in size by 30% or more.

One of the patients who achieved a PR had previously been determined to be resistant to paclitaxel, a chemotherapy agent commonly used in ovarian cancer. In that patient, the PR was observed when Cantrixil was combined with paclitaxel, suggesting that the drug may restore sensitivity to this chemotherapy agent. This finding is highly consistent with the preclinical data collected at Yale University, which demonstrated the ability of Cantrixil to re-sensitise tumours to paxlitaxel in mouse models of ovarian cancer.

A median progression free survival (PFS) of 5.5 months was calculated for the nine patients treated with Cantrixil in Part A. A previous study in a broadly comparable patient group reported a median PFS of 3.4 months for patients treated with chemotherapy alone[1]. While any comparison between studies must be treated with caution, this data suggests that

[1] Pujade-Lauraine E, Hilpert F, Weber B, et al. Bevacizumab combined with chemotherapy for platinum resistant recurrent ovarian cancer: The AURELIA open label randomized phase III Trial. *J Clin Oncol* 2014; 32 (13): 1302-8.

Cantrixil may, on average, be able to delay tumour recurrence in a group of patients with very advanced disease.

[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 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 2018. Initial safety data was released in May 2019, and further 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. Interim data was presented at the ESMO Congress in September 2019, and the study remains ongoing. Cantrixil was granted orphan designation for ovarian cancer by the US FDA in April 2015.