ASX RELEASE

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PAXALISIB PHASE II STUDY COMPLETES RECRUITMENT; KAZIA TO PRESENT NEW DATA AT AACR CONFERENCE IN APRIL 2020

Sydney, 6 March 2020 – Kazia Therapeutics Limited (ASX: KZA; NASDAQ: KZIA), an Australian oncology-focused biotechnology company, is pleased to provide an update to shareholders on recent progress with the development of paxalisib (formerly GDC-0084), its clinical-stage program in brain cancer.

Key Points

- Recruitment of patients to phase II study in glioblastoma is now complete
- New interim data to be presented at AACR in April 2020
- Good progress in set-up work for GBM AGILE, with patient recruitment planned to commence in 2H CY2020

Kazia CEO, Dr James Garner, commented, "It has been an exceptionally productive start to 2020 for the paxalisib program, and we are delighted with progress. Our ongoing phase II study in glioblastoma has completed recruitment, well ahead of expectations, and we expect to report new interim data in April 2020 at the AACR conference. Meanwhile, work is well underway to bring paxalisib into the GBM AGILE study, which is intended to provide a streamlined path to registration for the drug."

Completion of Recruitment to Phase II Study

Kazia commenced a phase II clinical trial in newly-diagnosed glioblastoma in 2018 (NCT03522298). The primary purpose of this study was to transition paxalisib from the very late-stage population that was studied in phase I to the newly-diagnosed patients that represent the target population for the commercial product.

The final patient in this study commenced dosing on 27 February 2020, and the study is now closed to recruitment. In total, 30 patients were recruited at six sites in the United States: 9 in Part A (a dose escalation component to study dosing), and 21 in Part B (a dose expansion cohort to seek preliminary signals of efficacy).

Kazia reported top-line safety data in May 2019. Specifically, a maximum tolerated dose (MTD) of 60mg was determined for the newly-diagnosed population, which exceeded the previous MTD in late-stage patients of 45mg. The dose-limiting toxicities (DLTs) included oral mucositis (mouth ulcers) and hyperglycemia (elevated blood sugar).

Initial efficacy data was presented in November 2019 at the Society for Neuro-Oncology (SNO) Annual Scientific Meeting in Phoenix, AZ. This interim read-out included data from the first nine patients enrolled to the study, representing the whole of Part A. A median progression-free survival (PFS) of 8.4 months was determined, which compares favourably to the existing standard of care at 5.3 months. Overall survival (OS) could not be calculated since three-quarters of evaluable patients remained alive at the time of data cut-off.

New Data to be Presented at AACR in April 2020

Kazia is pleased to have been accepted for a poster presentation at the prestigious American Association for Cancer Research (AACR) annual meeting in San Diego, CA. The conference will take place between 24 – 29 April 2020. The AACR meeting is one of the world's largest gatherings of cancer researchers and physicians, and also provides a rich opportunity for engagement with investors and potential partners.

Kazia anticipates that the AACR poster presentation will provide additional data from the ongoing phase II clinical study, building on the promising signals that were reported in November 2019.

Progress Continues Across Broader Paxalisib Program

In addition to the ongoing phase II study in glioblastoma, four additional studies are underway in other forms of brain cancer (NCT03994796, NCT03765983, NCT03696355, and NCT04192981). All four studies are actively recruiting patients. Kazia looks forward to providing progress updates and, where possible, interim data from these studies throughout calendar 2020.

Set-up work is well advanced with GBM AGILE (NCT03970447), Kazia's planned pivotal study, which is expected to provide the basis for an eventual product registration. At this stage, Kazia is planning to begin patient enrolment in the second half of calendar 2020.

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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 paxalisib (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, paxalisib entered a phase II clinical trial in 2018. Interim data was reported in November 2019, and further data is expected in 1H 2020. Paxalisib 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.

This announcement was authorized for release to the ASX by James Garner, Chief Executive Officer, Managing Director.