ASX ANNOUNCEMENT

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KAZIA THERAPEUTICS ANNOUNCES CLINICAL COLLABORATION FOR AUSTRALIAN PHASE II PRECISION MEDICINE STUDY OF PAXALISIB IN CHILDHOOD CANCERS

Sydney, 7 March 2023 – Kazia Therapeutics Limited (NASDAQ: KZIA; ASX: KZA), an oncology-focused drug development company, is pleased to announce that it has entered into a collaboration with the Australian and New Zealand Children's Haematology / Oncology Group (ANZCHOG) for a phase II clinical study examining paxalisib in children with advanced solid tumours, including brain tumours.

The study, named OPTIMISE, will combine paxalisib with chemotherapy for children with specific genetic mutations in their tumours. The study will harness expertise and insights gained from the Zero Childhood Cancer Program, which aims to match childhood cancer patients with targeted therapies suited to the unique characteristics of their tumour.

Key Points

- New collaboration is the first Australian-led clinical trial of paxalisib.
- Zero Childhood Cancer Program, led out of the Children's Cancer Institute and the Kids Cancer Centre at Sydney Children's Hospital, has already enrolled more than 900 children with high-risk malignancies. Patients with PI3K pathway alterations may now be eligible to receive paxalisib.
- OPTIMISE will explore paxalisib in combination with existing chemotherapy agents for the treatment of children with high-risk malignancies, including (but not confined to) brain tumours. It will first seek to establish the optimal dosing for children in combination with chemotherapy and will then determine the efficacy and safety in biomarker-defined populations.
- Up to 18 children are anticipated to be enrolled into an initial dose escalation cohort, and up to 100 patients in a dose expansion cohort.

- The study is funded by the Australian Government, through a Medical Research Future Fund (MRFF) grant, with Kazia's contribution consisting of drug supply and in-kind support.

"We are pleased to see this very exciting new trial move forward with paxalisib as a matched targeted therapy in a biomarker-selected paediatric population," said Dr James Garner, Chief Executive Officer of Kazia. "Our commitment to childhood cancer, especially childhood brain cancer, is already substantial. The OPTIMISE study is very complementary to the ongoing PNOC022 study in DIPG, and in addition represents a promising new opportunity to explore paxalisib in a broader range of patients. This new project speaks to the substantial ongoing interest in the drug among leading clinicians and has the potential to yield important new insights into the use of paxalisib in some new areas with very substantial unmet clinical need."

Zero Childhood Cancer Program

The Zero Childhood Cancer Precision Medicine Program (ZERO) is an international effort to identify targeted therapies for childhood malignancies. One of the key insights of recent decades in cancer treatment has been the understanding that tumours are typically driven by specific genetic mutations. Instead of taking a 'one size fits all' approach to their treatment, ZERO aims to provide tailored individual treatment regimens for children diagnosed with cancer.

ZERO is led by the Children's Cancer Institute and the Kid's Cancer Centre at Sydney Children's Hospital, Randwick in Sydney, NSW. The Institute is a leading Australian Medical Research Institute dedicated to paediatric cancer. The principal investigators of the paxalisib arm of the OPTIMISE study are Dr Marion Mateos and Professor David Ziegler, senior clinicians at the Kids Cancer Centre with extensive track records in the field.

Next Steps

OPTIMISE is expected to commence enrolment in 2H CY2023. The study will initially launch in Australia but may expand in due course to other countries.

An international phase II study of paxalisib in combination with ONC-201 for the treatment of DIPG and DMGs, sponsored by the Pacific Pediatric Neuro-Oncology Consortium (PNOC), commenced recruitment in November 2021. Initial data is anticipated in 1H CY2023.

About Kazia Therapeutics Limited

Kazia Therapeutics Limited (NASDAQ: KZIA; ASX: KZA) is an oncology-focused drug development company, based in Sydney, Australia.

Our lead program is paxalisib, a brain-penetrant inhibitor of the PI3K / Akt / mTOR pathway, which is being developed to treat multiple forms of brain cancer. Licensed from Genentech in late 2016, paxalisib is or has been the subject of ten clinical trials in this disease. A completed phase II study in glioblastoma reported promising signals of efficacy in 2021, and a pivotal study for registration, GBM AGILE, is ongoing, with final data expected in CY2023. Other clinical trials are ongoing in brain metastases, diffuse midline gliomas, and primary CNS lymphoma, with several of these having reported encouraging interim data.

Paxalisib was granted Orphan Drug Designation for glioblastoma by the US FDA in February 2018, and Fast Track Designation for glioblastoma by the US FDA in August 2020. In addition, paxalisib was granted Rare Pediatric Disease Designation and Orphan Designation by the US FDA for DIPG in August 2020, and for atypical teratoid / rhabdoid tumours (AT/RT) in June 2022 and July 2022, respectively.

Kazia is also developing EVT801, a small-molecule inhibitor of VEGFR3, which was licensed from Evotec SE in April 2021. Preclinical data has shown EVT801 to be active against a broad range of tumour types and has provided compelling evidence of synergy with immuno-oncology agents. A phase I study commenced recruitment in November 2021.

For more information, please visit www.kaziatherapeutics.com or follow us on Twitter @KaziaTx.

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

Forward-Looking Statements

This announcement may contain forward-looking statements, which can generally be identified as such by the use of words such as “may,” “will,” “estimate,” “future,” “forward,” “anticipate,” or other similar words. Any statement describing Kazia's future plans, strategies, intentions, expectations, objectives, goals or prospects, and other statements that are not historical facts, are also forward-looking statements, including, but not limited to, statements regarding: the timing for results and data related to Kazia’s clinical and preclinical trials, and Kazia’s strategy and plans with respect to its programs, including paxalisib. Such statements are based on Kazia’s expectations and projections about future events and future trends affecting its business and are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements, including risks and uncertainties: associated with clinical and preclinical trials and product development, related to regulatory approvals, and the related to the impact of global economic conditions. These and other risks and uncertainties are described more fully in Kazia’s Annual Report, filed on form 20-F with the SEC, and in subsequent filings with the SEC. Kazia undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required under applicable law. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this announcement.