ASX ANNOUNCEMENT
15 December 2022

KAZIA LAUNCHES PRECLINICAL COLLABORATION WITH QIMR BERGHOFER MEDICAL RESEARCH INSTITUTE AND ANNOUNCES PATENT FILING

Sydney, 15 December 2022 – Kazia Therapeutics Limited (NASDAQ: KZIA; ASX: KZA), an oncology-focused drug development company, is pleased to announce a collaboration with QIMR Berghofer Medical Research Institute, one of Australia's foremost cancer research centres, to explore novel uses of paxalisib in solid tumours.

The research project is led by Professor Sudha Rao, a leading expert in transcriptional biology, particularly as it applies to the function of the immune system in cancer. Professor Rao's laboratory works closely with pharmaceutical companies and with clinicians to explore innovative approaches to cancer treatment.

The collaboration is ongoing and will build on initial research that has already led to the filing of a patent, including the use of paxalisib as an immune modulator in the treatment of diseases such as breast cancer.

Key Points

- Paxalisib is a member of a class of drugs known as PI3K inhibitors. The direct anti-cancer effects of PI3K inhibitors are well demonstrated, and five therapies have been approved by the US FDA to date.

- Professor Rao's research identifies an entirely separate effect of PI3K inhibition: as a modulator of the immune microenvironment within and around the tumour. Administration of PI3K inhibitors such as paxalisib, at doses and frequencies different to those conventionally used, appears to activate the immune system in the tumour, making it more susceptive to immunotherapy.

- The research opens up an important opportunity for paxalisib in combination with drugs such as Keytruda® (pembrolizumab, Merck) and Opdivo® (nivolumab, Bristol Myers Squibb) for the treatment of diseases such as breast cancer and lung cancer. If proven effective in clinical trials, such combinations may have the potential to improve outcomes for patients.

Board of Directors
Mr Iain Ross Chairman, Non-Executive Director
Mr Bryce Carmine Non-Executive Director
Mr Steven Coffey Non-Executive Director
Dr James Garner Chief Executive Officer, Managing Director

- It is anticipated that the results of the research will be published in 1H CY2023, and discussions are ongoing regarding potential translation to clinical trials in CY2023.

“These are very promising data,” commented Professor Rao, Principal Investigator on the project. “In treatment-resistant pre-clinical models of breast cancer, paxalisib has shown encouraging results in inhibiting both the primary tumour burden and metastasis by reinvigorating the immune system within the tumour microenvironment. We look forward to continuing our research, and hopefully seeing this work lead to a clinical trial in due course.”

“Professor Rao’s team are working at the leading edge of cancer research, and we are enormously grateful for their work on paxalisib,” said Dr James Garner, CEO of Kazia. “An important part of our recent strategy for the drug has been to expand its field of opportunity outside of cancers of the brain. This work, which has primarily focused on breast cancer, but which has applicability to other solid tumours, builds on some promising data we previously shared which demonstrated the potential of paxalisib in melanoma. We look forward to working with the QIMR Berghofer team to take this research to the next stage.”

For More Information, Please Contact:-

Jane Lowe
IR Department
jane.lowe@irdepartment.com.au
Phone: +61 411 117 774

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.

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 and EVT801. 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.