

Kazia Therapeutics Expands Ongoing Phase 1b Trial of Paxalisib in Advanced Breast Cancer

Planned Enrollment to Increase from 12 to 36 Patients Following Continued Encouraging Safety and Tolerability Data

SYDNEY, Australia, May 26, 2026 – Kazia Therapeutics Limited (NASDAQ: KZIA) (“Kazia” or the “Company”), a clinical-stage oncology company advancing therapies designed to reprogram cancer biology and overcome treatment resistance, today announced plans to expand its ongoing Phase 1b clinical trial evaluating lead asset paxalisib in combination with standard-of-care therapies in patients with advanced triple negative breast cancer (“TNBC”). Based on continued encouraging safety, tolerability and clinical activity data observed to date, planned enrollment has increased from 12 to 36 patients.

The expansion is intended to further evaluate the safety, tolerability, dose optimization and preliminary efficacy of the paxalisib-based combination regimen with pembrolizumab and chemotherapy. The expanded dataset is expected to provide a more meaningful assessment of objective response rate (“ORR”), progression-free survival (“PFS”) and translational biomarkers. Additional clinical trial updates are anticipated throughout 2026 and into 2027.

“We remain encouraged by the safety and tolerability data observed to date, and expanding enrollment allows us to generate a broader clinical and translational dataset as we advance paxalisib in difficult-to-treat advanced breast cancer, such as TNBC,” said Dr. John Friend, CEO, Kazia Therapeutics. “Paxalisib’s mechanism, modulating key resistance and immune-related pathways, addresses the very reasons that current therapies fail, and we believe it holds meaningful potential for an underserved patient population. While we planned to present scientific progress at ASCO 2026, we made the decision to withdraw our abstracts solely to protect our intellectual property position ahead of anticipated filings. The withdrawal was not related to any safety or clinical concerns. We expect to share additional clinical and translational updates in the coming months.”

The Phase 1b study is evaluating paxalisib in combination with established breast cancer regimens across multiple dose cohorts. The trial expansion is supported by a recently published preclinical study in *Molecular Cancer Therapeutics*, a journal of the American Association for Cancer Research (“AACR”), demonstrating that dual PI3K/mTOR inhibition with paxalisib altered tumor cell state and immune signaling in preclinical TNBC models. TNBC accounts for approximately 15 to 20 percent of all breast cancer diagnoses and is associated with poorer outcomes relative to other breast cancer subtypes.

About Kazia Therapeutics

Kazia Therapeutics (NASDAQ: KZIA) is an oncology-focused drug development company, based in Sydney, Australia. The Company’s lead asset, paxalisib, is an investigational brain penetrant inhibitor of the PI3K/Akt /mTOR pathway, which is being developed to treat multiple forms of cancer. Licensed from Genentech in late 2016, paxalisib is or has been the subject of 10 clinical trials. A completed Phase 2/3 study in glioblastoma (GBM-Agile) was reported in 2024, and discussions are ongoing for designing and executing a pivotal registrational study in pursuit of a standard approval.

Other clinical trials involving paxalisib are ongoing in advanced breast cancer, brain metastases, diffuse midline gliomas, and primary central nervous system lymphoma, with several of these trials having reported encouraging interim data. Paxalisib was granted Orphan Drug Designation for glioblastoma by the U.S. Food and Drug Administration (FDA) in February 2018, and Fast Track Designation (FTD) for glioblastoma in August 2020. Paxalisib was also granted FTD in July 2023 for the treatment of solid tumor brain metastases harboring PI3K pathway mutations in combination with radiation therapy.

Additionally, paxalisib was granted Rare Pediatric Disease Designation and Orphan Drug Designation by the FDA for diffuse intrinsic pontine glioma in August 2020 and for atypical teratoid / rhabdoid tumors 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. In addition to its clinical-stage programs, Kazia is advancing NDL2, a potentially first-in-class intracellular PD-L1 protein degrader program targeting a newly identified mechanism of immunotherapy resistance and metastatic progression, as well as MSETC, a potentially first-in-class SETDB1 inhibitor program intended to restore immune signaling in tumors that have become resistant to immunotherapy, including checkpoint inhibitors. Both programs are currently in preclinical development. For more information, please visit www.kaziatherapeutics.com or follow us on X @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," "expect," "plan," "believe," "potential," 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 planned expansion of the Phase 1b clinical trial of paxalisib in advanced TNBC; the anticipated increase in enrollment from 12 to 36 patients; expectations regarding the safety, tolerability, dose optimization and preliminary efficacy of paxalisib in combination with pembrolizumab and chemotherapy; the potential of paxalisib to treat advanced breast cancer, including TNBC; expectations regarding objective response rate, progression-free survival and translational biomarkers; anticipated timing of clinical trial updates throughout 2026 and into 2027; the timing and content of future public disclosures regarding the Company's clinical programs; the Company's decisions regarding the timing and manner of scientific presentations and publications, including the withdrawal of abstracts from scientific conferences for intellectual property-related reasons; and statements regarding the potential therapeutic benefit of paxalisib to modulate key resistance and immune-related pathways in difficult-to-treat breast cancer populations. Such statements are based on Kazia's current 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: the development of early-stage therapeutic programs; the conduct of clinical trials, including the ability to enroll patients and achieve anticipated enrollment targets; the preliminary nature of data from a small, open-label clinical study, which may not be predictive of later-stage clinical results; risks related to regulatory approvals; risks related to Kazia's reliance on third-party collaborators and clinical trial sites; risks related to the Company's ability to obtain, maintain and protect its intellectual property, including decisions regarding the timing and manner of scientific disclosures; risks related to the impact of global economic conditions; and risks related to Kazia's ability to maintain compliance with the applicable NASDAQ continued listing requirements and standards. These and other risks and uncertainties are described more fully in Kazia's Annual Report on Form 20-F filed with the SEC, and in subsequent filings with the United States Securities and Exchange Commission. 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.

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