Kazia Therapeutics Reports Encouraging Preliminary Clinical Responses in Ongoing Phase 1b Study of Paxalisib in Late-Stage Metastatic Triple-Negative Breast Cancer

Sydney, Australia, January 27, 2026; Kazia Therapeutics (NASDAQ: KZIA), today provided a clinical update from its ongoing Phase 1b study evaluating paxalisib in combination with pembrolizumab and chemotherapy in patients with late-stage (Stage IV), metastatic triple-negative breast cancer (TNBC).

To date, three patients with metastatic TNBC treated with paxalisib-based regimens have demonstrated meaningful clinical responses, including two partial responses (PRs) in trial participants and one confirmed complete metabolic response (CR) in a patient treated under an expanded access program.

Clinical Highlights

- 2 of 2 evaluable patients enrolled in the Phase 1b trial achieved partial responses
- One advanced metastatic TNBC patient achieved a confirmed complete metabolic response following re-treatment with pembrolizumab/chemotherapy plus paxalisib (under an expanded access protocol)
- Responses observed in patients with visceral disease and multi-organ metastases
- Median time on treatment to date is approximately 6.1 months, with all patients continuing on therapy at the time of this update
- Paxalisib continues to demonstrate a generally favorable safety and tolerability profile when combined with pembrolizumab and chemotherapy at the 30 mg daily dose

The ongoing Phase 1b trial is a multi-center, open-label, randomized study initiated in June 2025 designed to evaluate the safety, tolerability, and preliminary clinical activity of paxalisib in patients with advanced breast cancer, including TNBC, in combination with either: Pembrolizumab plus chemotherapy (current standard-of-care first-line regimen) or Olaparib (advanced breast cancer patients with BRCA mutations). Eligibility for the pembrolizumab-containing cohort required PD-L1–positive disease (CPS ≥10), consistent with standard-of-care practice in metastatic TNBC.

Patient 1 – Partial Response
A 61-year-old female with metastatic TNBC involving the left upper lobe of the lung, initiated treatment with paxalisib (30 mg daily) in combination with pembrolizumab and gemcitabine/carboplatin in June 2025. After nine cycles of therapy, serial imaging demonstrated continued tumor reduction at each assessment, culminating in a partial response by iRECIST criteria. The patient remains active on study.

Patient 2 – Partial Response with Complete Resolution of a Target Lesion
A 47-year-old female with extensively metastatic TNBC involving the lung, liver, bone, and lymph nodes, initiated treatment with paxalisib (30 mg daily) in combination with pembrolizumab and gemcitabine/carboplatin in October 2025. Following three treatment cycles, imaging demonstrated a partial response, including complete resolution of a target lung lesion and the patient remains active on study.

Patient 3 – Confirmed Complete Metabolic Response
A 44-year-old female with metastatic TNBC who had previously received pembrolizumab/chemotherapy experienced disease progression involving bone and lung

metastases in early 2025. Although ineligible for the formal trial due to prior pembrolizumab exposure, the patient was re-treated beginning in June 2025 with pembrolizumab/chemotherapy plus paxalisib (30 mg daily) under physician supervision. On November 10, 2025, FDG PET/CT imaging demonstrated no evidence of active malignancy, consistent with a complete metabolic response. This complete metabolic response was confirmed on follow-up imaging in January 2026, and the patient remains on paxalisib and pembrolizumab therapy.

Paxalisib has been generally well tolerated in combination with pembrolizumab and chemotherapy. Approximately 75% of adverse events (AEs) were assessed as unlikely or unrelated to paxalisib. The paxalisib-related AEs were expected and predominantly mild to moderate, consistent with prior studies. At the 30 mg daily dose, one case of Grade 1 hyperglycemia has been observed, requiring no intervention. Two serious adverse events (SAEs) have been reported to date, both deemed unrelated to paxalisib.

Following an initial targeted site activation phase designed to ensure rigorous protocol execution and informed by encouraging early clinical signals from the first patients treated, the Company expects to activate two additional clinical sites by April 2026, with two further sites planned for mid-2026. Kazia continues to anticipate the targeted enrollment of twelve TNBC pts target by the end of 2026 and topline data readout in early 2027

Kazia is also evaluating paxalisib in additional breast cancer populations, including earlier-stage TNBC and hormone receptor–positive, HER2-negative (HR+ / HER2-) breast cancer, where dysregulation of the PI3K/mTOR pathway is well established. Paxalisib's oral, once-daily administration offers a potentially convenient treatment option with minimal incremental burden to patients and clinical sites, an important consideration as the Company explores expansion into broader breast cancer populations. The Company will provide updates as these programs advance.

"While these observations represent a preliminary read from ongoing studies, the consistency and depth of responses we are seeing including tumor regression across multiple metastatic sites and a complete metabolic response are highly encouraging," said Dr. John Friend, M.D., Chief Executive Officer of Kazia Therapeutics. "Confirmed complete responses in metastatic triple-negative breast cancer are exceedingly rare, particularly in patients who have already progressed on standard therapies. These early data reinforce our belief that paxalisib has the potential to meaningfully enhance the activity of existing immunotherapy-based regimens, and we look forward to generating additional clinical and translational insights throughout the year."

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About Kazia Therapeutics

Kazia Therapeutics Limited (NASDAQ: KZIA) is an oncology-focused drug development company, based in Sydney, Australia. Our lead program is paxalisib, 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 ten clinical trials in this disease. 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 by the FDA 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. In addition, 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. Preclinical data has shown EVT801 to be active against a broad range of tumor types and has provided evidence of synergy with immuno-oncology agents. In addition to its clinical-stage programs, Kazia is advancing NDL2, a potentially first-in-class nuclear PD-L1 protein degrader program targeting a newly identified mechanism of immunotherapy resistance and metastatic progression, 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," 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, the plan to activate additional clinical sites for the Phase 1b study in 2026, the anticipated completion of enrolment in the Phase 1b clinical trial in the fourth quarter of 2026, the anticipated topline data readout in early 2027, the potential of paxalisib's oral, once-daily administration to offer a convenient treatment option with minimal incremental burden to patients and clinical sites, the opportunities of evaluating paxalisib in additional breast cancer populations, and the potential benefits of paxalisib. 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 clinical and preclinical trials and product development, including the risk that interim or early data may not be consistent with final data, risks related to regulatory approvals, risks related to the impact of global economic conditions, and risks related to Kazia's ability to regain and/or 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, filed on form 20-F 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.