Kazia Therapeutics Achieves Initial iCR (Immune-Complete Response) in Metastatic TNBC and Delivers Q4 Business Update with Breakthroughs Across Breast Cancer, Immuno-Oncology, and GBM Regulatory Strategy

Sydney, 18 November 2025: Kazia Therapeutics Limited (Nasdaq: KZIA), an oncology-focused drug development company, today announced that a patient with stage IV triple-negative breast cancer (TNBC) treated under an FDA-authorized single-patient expanded access protocol combining paxalisib with pembrolizumab (Keytruda®) and standard chemotherapy has achieved an initial immune-complete response (iCR) per iRECIST criteria. This outcome suggests a profound radiologic response in a highly aggressive metastatic cancer subtype.

This development builds upon Kazia's October 2, 2025 announcement reporting an 86% reduction in tumor burden after only three weeks of treatment in the same patient. A PET/CT scan performed after approximately three months of therapy demonstrated complete metabolic resolution of all previously identified lesions, consistent with an initial iCR. The patient remains on therapy and under active clinical monitoring. A follow-up scan will be conducted in accordance with immune-based response assessment guidelines to confirm the initial scan.

Complete responses in stage IV metastatic TNBC are exceedingly uncommon across many therapeutic classes, including immunotherapy, chemotherapy, and antibody–drug conjugates. For example, pembrolizumab monotherapy has demonstrated complete response rates of approximately 0.6–4% in metastatic TNBC across KEYNOTE studies, and even the most active approved agents—such as sacituzumab govitecan—have reported complete response rates of only ~2–4% in large Phase 2 and Phase 3 trials.

In this setting, any radiologic finding consistent with an immune-complete response (iCR), even prior to confirmatory imaging, represents a highly unusual event which stands out relative to historical benchmarks for metastatic TNBC. These data may suggest enhanced biological activity of the combination regimen and warrant continued follow-up under iRECIST guidelines.

"Observing an initial complete response in a patient with metastatic triple-negative breast cancer is an extremely encouraging clinical finding," said Dr. John Friend, Chief Executive Officer of Kazia Therapeutics. "Although this is a single expanded-access case and requires confirmatory imaging, the depth of response aligns closely with our mechanistic hypothesis that paxalisib may meaningfully enhance anti-tumor immunity when combined with checkpoint blockade. This outcome further energizes our Phase 1b program in advanced breast cancer and complements significant progress across our broader pipeline."

Q4 BUSINESS UPDATE

1. Kazia Announces upcoming presentations related to paxalisib and NDL2 programs

    Kazia is pleased to announce the acceptance of two scientific presentations at the 2025 Brisbane Cancer Conference, scheduled to take place on 27–28 November 2025 in Brisbane, Australia.

    The Brisbane Cancer Conference is a premier oncology meeting that brings together leading international researchers, clinicians and industry experts working in the fields of translational oncology, molecular medicine and cellular therapeutics.

The following presentations will take on November 27, 2025:

"From bench to bedside: targeting epigenetic pathways to overcome metastasis and immunotherapy resistance in TNBC" – Sudha Rao, PhD, QIMR Berghofer (Australia)

Epigenetic checkpoint blockade: A new booster to enhance immunogenicity" Sherry Tu, PhD, QIMR Berghofer (Australia)

Kazia is proud to announce acceptance of two scientific presentations at the 2025 San Antonio Breast Cancer Symposium (SABCS) to be held December 10–14, 2025. SABCS is the largest and most influential breast cancer meeting globally, drawing more than 10,000 international experts in clinical oncology, translational science, immunotherapy, and molecular diagnostics.

December 10, 2025 — PS2-10-02

"Liquid Biopsy Tracking of PI3K-mTOR Residual Disease Signatures in Metastatic Breast Cancer", Presenter: Prof. Sudha Rao, QIMR Berghofer (Australia)

December 12, 2025 — PS5-08-04

"A Phase 1b, Multi-Centre, Open-Label, Randomized Study to Evaluate the Safety, Tolerability, and Clinical Activity of Combining Paxalisib with Olaparib or Pembrolizumab/Chemotherapy in Patients with Advanced Breast Cancer", Presenter: Dr. Michelle Nottage, The Royal Brisbane and Women's Hospital (Australia)

"SABCS is the pinnacle global meeting for breast cancer research. Being selected for two presentations is both an honor and a strong validation of our scientific direction," stated Dr. Friend.

2. NDL2 PD-L1 Degrader Program: Advancing Toward IND-Enabling Studies anticipated in Early 2026

As announced in September 2025, Kazia entered into a collaboration and licensing agreement with QIMR Berghofer covering the first in class NDL2 PD-L1 degrader program. PD-L1 degraders represent the next frontier in immuno-oncology, using a dual-mechanism approach is designed to specifically recognize and degrade the resistant, post-translationally modified forms of the PD-L1 protein. This strategy may address resistance mechanisms that limit current checkpoint inhibitors. Kazia expects to initiate IND-enabling preclinical studies in early 2026.

3. GBM Program: Advancing Toward a FDA Type C Meeting Request Following Strong Overall Survival Signals

As detailed in the October 24, 2025 press release, Kazia intends to request a follow-up Type C meeting with the FDA to discuss the overall survival paxalisib findings from our completed clinical studies, alignment with the Project FrontRunner framework, potential requirements for a confirmatory study, and elements needed for a possible NDA submission pathway for paxalisib in newly diagnosed glioblastoma.

"We believe paxalisib's OS data strongly justify continued engagement with the FDA and may support a more efficient regulatory strategy under Project FrontRunner," stated Dr. Friend.

4. As previously disclosed, Kazia received a notice (the "Notice") from the Listing Qualifications department (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") on May 12, 2025 notifying the Company that from March 28, 2025 to May 9, 2025, the Company's Market Value of Listed Securities ("MVLS") was below the minimum of $35 million required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(b)(2) (the "MVLS Requirement"). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), Nasdaq provided the Company with 180 calendar days, or until November 10, 2025 to regain compliance with the MVLS Requirement.

On November 12, 2025, Kazia received a staff determination letter ("Staff Letter") from the Staff of Nasdaq indicating that the Company had not regained compliance with the MVLS Requirement by November 10, 2025. Pursuant to the Nasdaq Listing Rules and the Staff Letter, unless the Company timely requests a hearing before a Hearings Panel (the "Panel"), the Company's American Depositary Shares would be subject to suspension/delisting . The Staff Letter has no immediate effect on listing or trading, and the Company intends to timely request a hearing before the Panel, which will automatically stay any suspension or delisting action pending the outcome of the hearing. The Company believes there are remedies available to potentially stop the proceedings and is evaluating corporate and market-based options, including alternative Nasdaq equity requirements to regain compliance.

For investor and media, please contact Alex Star, Managing Director LifeSci Advisors LLC, Astarr@lifesciadvisors.com, +1-201-786-8795.

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. A Phase I study has been completed and preliminary data was presented at 15th Biennial Ovarian Cancer Research Symposium in September 2024. For more information, please visit www.kaziatherapeutics.com or follow us on X @KaziaTx.

Forward-Looking Statements

This announcement contains forward-looking statements, which can generally be identified as such by the use of words such as "may," "will," "plan," "intend," "estimate," "future," "forward," "potential," "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: additional confirmatory imaging and analysis to be performed on the TNBC patient treated with paxalisib and pembrolizumab (Keytruda®), the potential benefits of NDL2 and the plans and goals of developing NDL2 formulation, the anticipated development pathways and combinations of NDL2, the timing for results and data related to Kazia's clinical and preclinical trials, the upcoming scientific presentations, Kazia's intention to request and hold a Type C meeting with the FDA to discuss OS findings in GBM patients treated with paxalisib and to seek agency feedback on a potential regulatory pathway, the plan to propose initiation of the post-approval, randomized Phase 3 confirmatory study prior to submission of the NDA, the intention to present survival analyses, supporting clinical safety and planned confirmatory trial design for FDA discussion, Kazia's intention to reference Project FrontRunner principles in its Type C briefing package, the objective to work collaboratively with the FDA under the guiding principles of Project FrontRunner, the plan to pursue a conditional approval in the front-line treatment setting of GBM, the plan to initiate the post-approval, randomized Phase 3 study prior to filing the NDA, the goal of ensuring that Kazia's development plan and regulatory strategy fully reflects and aligns with the FDA's framework and emphasis, the timing for results and data related to Kazia's clinical and preclinical trials, Kazia's strategy and plans with respect to its paxalisib program, the potential benefits of paxalisib, timing for any regulatory submissions or discussions with regulatory agencies and the potential market opportunity for paxalisib, regaining compliance with the MVLS Requirement and any other Nasdaq listing requirements, the timing and likelihood of requesting and successfully completing a hearing before the Panel and maintaining Kazia’s listing on Nasdaq. 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 most recent 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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