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# Kazia Therapeutics Highlights Recent Progress and Provides Business Update

Awarded research grant from The Michael J. Fox Foundation for Parkinson's Research (MJFF) to fund research between The Hebrew University of Jerusalem (Hebrew University) and Kazia to explore the therapeutic potential of paxalisib as a treatment for Parkinson's disease (PD)

Launched clinical trial evaluating the combination of paxalisib and immunotherapy in patients with advanced breast cancer

Reached alignment with the FDA on key aspects of the design of a proposed registrational/pivotal phase 3 study of paxalisib for treatment of glioblastoma (GB), including patient population, primary endpoint, and comparator arm

Raised \$3 million in capital during the first quarter of 2025, which included \$1 million in non-dilutive funding

Sydney, May 15, 2025 – Kazia Therapeutics Limited (NASDAQ: KZIA) ("Kazia" or the "Company"), an oncology-focused drug development company, today announced a summary of its recent progress across its business and also provided a business update.

"During the first quarter of 2025, we made significant progress both with respect to our clinical programs and corporate strategy," said John Friend, M.D., Chief Executive Officer of Kazia Therapeutics. "We recently advanced paxalisib into multiple new clinical trials, reached the last patient follow-up in a Phase 1 trial of EVT801 for the treatment of solid tumours, and raised \$3 million in new capital, including \$1 million in non-dilutive funding."

"Looking ahead, we anticipate a busy year for Kazia, as both paxalisib and EVT801 continue to advance across multiple clinical trials based on strong investigator interest. We are excited about the potential of our advanced-stage pipeline candidates to address significant areas of unmet need within oncology, and we look forward to providing additional updates on our progress throughout 2025."

## Pipeline - paxalisib

On February 20, 2025, the Company announced a research grant awarded from The Michael
J. Fox Foundation for Parkinson's Research (MJFF) to fund research between The Hebrew
University of Jerusalem (Hebrew University) and Kazia to explore the therapeutic potential of
paxalisib as a treatment for Parkinson's disease (PD). The grant will fund collaborative
preclinical studies at Professor Ronit Sharon's lab (Hebrew University) aimed at establishing
an operational link between a specific pathway in the pathophysiology of PD and paxalisib.
The research will assess the impact of paxalisib on mouse survival, motor and non-motor
performances, as well as specific biochemical, pathological and molecular disease
biomarkers that will be determined in brains of treated mice. Data from this research is
expected to provide valuable insights into its potential activity for the treatment of PD.

- In February 2025, Kazia executed an agreement to evaluate paxalisib in the next-Generation aGile Genomically Guided Glioma platform (5G) study. The 5G study is an academic trial conducted by the Drug Development Unit Investigator Initiated Team and sponsored by the Institute of Cancer Research, London and fully funded by Cancer Research UK and the Australian charity, Minderoo Foundation. Every patient in this study will have their genome sequenced, enabling researchers to target their treatment with greater precision. Patients with PI3k/mTOR related mutations will be enrolled to receive paxalisib once a day.
- On January 30, 2025, the Company announced the regulatory approval and launch of a clinical trial evaluating the combination of paxalisib and immunotherapy in patients with advanced breast cancer. This novel treatment combination offers what is believed to be a unique approach to targeting this highly aggressive and treatment-resistant type of breast cancer. The ABC-Pax (Advanced Breast Cancer Paxalisib) study is the first known trial conducted to assess the safety and efficacy of paxalisib in combination with KEYTRUDA® (pembrolizumab) or LYNPARZA® (olaparib) in women with triple negative breast cancer. ABC-Pax is a multi-center, open-label phase 1b study that will enroll 24 patients who will receive the combination therapy for up to 12 months. Currently the study is open and actively screening patients at The Royal Brisbane and Women's Hospital, Gold Coast University Hospital and Sunshine Coast University Hospital in Queensland, Australia with plans to open up to 4 additional sites in Australia.
- On December 31, 2024, the Company provided a regulatory update on paxalisib for the treatment of glioblastoma (GBM) following its Type C clinical meeting with the United States Food and Drug Administration (FDA). The FDA's current position is that data on overall survival (OS) would generally not be appropriate for accelerated approval but could be considered to support a traditional/standard approval. The FDA further commented that the secondary endpoint OS data from the GBM-AGILE study are supportive and informative for designing and executing a pivotal registrational study in pursuit of a standard approval. Importantly, the Company aligned with the FDA on key aspects of the design of a proposed registrational/pivotal phase 3 study, including patient population, primary endpoint, and the comparator arm to be used.
  - The study will be a randomized, controlled study of paxalisib versus standard of care (SOC) in patients with newly diagnosed unmethylated glioblastoma to determine Overall Survival as well as other parameters of clinical efficacy, safety and tolerability. Approximately 366 patients will be enrolled over 14 months into the study with a 1:1 treatment ratio between the paxalisib and SOC (temozolomide) arm. We anticipate engaging roughly 50 clinical sites across the globe (North America, UK, Europe, Asia-Pacific) for this study. The Kazia team is exploring various bids from Contract Research Organizations (CROs) in parallel to discussions with strategic partners and cooperative groups to participate or fully fund the trial.

#### Pipeline – EVT801

 In November 2024, the last patient completed follow-up in a Phase 1 study (NCT05114668) evaluating EVT801 for the treatment of patients with histologically-confirmed advanced or metastatic solid tumours, unresponsive to standard treatment, or for whom no standard treatment is available or appropriate. We anticipate receiving the final data in 2Q2025 and presenting data later this year at an international medical congress.

## Corporate

- On May 12, 2025, the Company received a notification (the Notification) from the Listing Qualifications Staff of the Nasdag Stock Market LLC (Nasdag) notifying the Company that 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. The Notification has no immediate impact on the Company's operations or listing and Kazia's American Depositary Shares (ADSs) will continue to trade on the Nasdaq Capital Market under the ticker "KZIA". In accordance with Nasdaq Listing Rule 5810(c)(3)(C), the Company has 180 calendar days to regain compliance with the MVLS Requirement. The Notification states that, to regain compliance with the MVLS Requirement, the Company's MVLS must close at \$35 million or more for a minimum of ten consecutive business days during the compliance period ending on November 10, 2025. Kazia has no intention of delisting and is currently exploring options to regain compliance, which include raising additional capital and possible merger and acquisition-related strategies. While the Company is exercising diligent efforts to maintain the listing of its ADS on Nasdaq, there can be no assurance that the Company will be able to regain or maintain compliance with the applicable continued listing standards set forth in the Nasdaq Listing Rules.
- Effective April 17, 2025, Kazia changed the ratio of its ADSs to Ordinary Shares from one ADS representing one hundred Ordinary Shares to one ADS representing five hundred Ordinary Shares. This adjustment, equivalent to a one-for-five reverse ADS split, was necessary to maintain compliance with Nasdaq's minimum bid price requirement.
- On March 31, 2025, the Company announced the sale of all intellectual property and trademarks rights to Cantrixil for USD \$1 million. In March 2021, Vivesto licensed the exclusive global development and commercialization rights for Cantrixil from Kazia Therapeutics. Having decided not to pursue the development of Cantrixil in ovarian cancer, as originally anticipated under the license, Vivesto is currently exploring Cantrixil preclinically for the treatment of hematological cancers.
- On February 26, 2025, CEO Dr John Friend bought 8,000 ADSs (split adjusted). The ADSs were bought at a split-adjusted price of \$4.2465 per ADS for a total transaction of \$33,972.
- On January 14, 2025, the Company announced the closing of a registered direct offering with existing fundamental healthcare investor, Alumni Capital LP. The gross proceeds to the

Company from the offering were approximately \$2.0 million, before deducting the placement agent's fees and other offering expenses payable by the Company.

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

#### **About Kazia Therapeutics Limited**

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 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 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 brain metastases, diffuse midline gliomas, and primary CNS lymphoma, with several of these trials having reported encouraging interim data. Paxalisib was granted Orphan Drug Designation for glioblastoma by the 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 tumour 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 tumours 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 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 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, Kazia's strategy and plans with respect to its programs, including paxalisib and EVT801, potential results of research between Hebrew University and Kazia regarding the therapeutic potential of paxalisib for the treatment of Parkinson's disease, the potential benefits of paxalisib as an investigational PI3K/mTOR inhibitor, timing for any regulatory submissions or discussions with regulatory agencies, the potential market opportunity for paxalisib and Kazia's intent and efforts to regain and/or maintain compliance with the applicable Nasdaq continued listing requirements and standards. 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, related to regulatory approvals, related to the impact of global economic conditions, and 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.

This announcement was authorized for release by Dr John Friend, CEO