Kazia Therapeutics announces the launch of a groundbreaking trial with paxalisib in combination with immunotherapy in women with advanced breast cancer

Sydney; 30 January 2025: Kazia Therapeutics Limited (NASDAQ: KZIA) an oncology-focused drug development company, is pleased to announce 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-centre, open-label phase 1b study that will enroll 24 patients from top cancer centres in Queensland, Australia and patients will receive the combination therapy for up to 12 months.

The ABC-Pax study stems from pivotal research led by QIMR Berghofer scientists in collaboration with Kazia Therapeutics, which combined its drug candidate, paxalisib, with immunotherapy in pre-clinical models. The team discovered that this combination approach triggers a novel molecular program by epigenetic re-programming of dormant cancer cells, making them visible to the immune system, while also reinvigorating the immune cells to fight the tumour cells. These new preclinical data were presented at San Antonio Breast Cancer Symposium on December 12, 2024, and highlight the potential therapeutic synergies between paxalisib and checkpoint inhibitor pembrolizumab (KEYTRUDA®), as well as between paxalisib and poly (ADP-ribose) polymerase inhibitor olaparib (LYNPARZA®), when used in combination in a preclinical model of immunotherapy-resistant triple negative breast cancer. The clinical trial is open for enrollment at the Royal Brisbane and Women's Hospital and plans to expand to other sites in Australia.

Kazia Therapeutics CEO, Dr John Friend, said the novel combination treatment may have the potential to transform the treatment of triple-negative breast cancer and other aggressive tumour types.

"The novelty of the science that Professor Rao has proposed with this dual combination of paxalisib and immunotherapy could advance the treatment of women with aggressive breast cancer, and we are excited to support this unique clinical study," Dr John Friend, CEO Kazia Therapeutics said.

QIMR Berghofer's Professor Sudha Rao said, "There is no cure for triple negative breast cancer and the life expectancy for these women is tragically short. We want to identify treatments to extend the duration and quality of life of these patients. The hope is to prolong patient survival through the new combined therapy, which targets the dormant cancer cells that drive the spread and recurrence of the disease and rejuvenates the immune system to more effectively fight the cancer."

The ABC-Pax trial will also evaluate a non-invasive liquid biopsy digital pathology platform developed by Professor Rao and her team, which can monitor the behaviour of cancer cells and immune cells in real time from a blood sample.

"By regularly analysing blood samples from trial participants using our liquid biopsy digital pathology platform, we can track the effectiveness of the treatment in real time. We believe this approach represents a major advance in precision medicine by offering a faster and more accurate way to monitor patient progress," Professor Rao said.

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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, the ABC-Pax study and the potential results of combination studies of paxalisib, the potential benefits of paxalisib as an investigational PI3K/mTOR inhibitor, timing for any regulatory submissions or discussions with regulatory agencies, and the potential market opportunity for 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, related to regulatory approvals, and 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 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.