

4 November 2024

## ***Kazia Therapeutics Announces Granting of Type C Meeting with FDA to Discuss Potential Next Steps for Paxalisib in the Treatment of Newly Diagnosed Glioblastoma Multiforme***

*Company and FDA to meet in December to discuss potential pathways to registration of paxalisib in glioblastoma multiforme (GBM)*

*Company updates to corporate presentation and participation in upcoming medical meetings*

Sydney, November 4, 2024 – Kazia Therapeutics Limited (NASDAQ: KZIA), an oncology-focused drug development company, announced that the U.S. Food and Drug Administration (FDA) has granted a Type C meeting with the Company in December 2024 to discuss the potential pathways to registration of Kazia’s blood brain barrier penetrant PI3K/mTOR inhibitor, paxalisib, for the treatment of patients with newly diagnosed GBM.

In July 2024, the Company announced results from the Phase II/III clinical trial, GBM-AGILE, in which newly diagnosed unmethylated patients with glioblastoma treated with paxalisib showed clinically meaningful improvement in a prespecified secondary analysis for overall survival. Full data including secondary endpoints from the paxalisib arm of the GBM-AGILE study is expected to be presented at a scientific meeting later this year.

Paxalisib has previously received orphan drug designation and fast track designation from the FDA for glioblastoma in unmethylated MGMT promoter status patients, following radiation plus temozolomide therapy.

### **Updated corporate presentation**

Today, the Company also announced that it has updated its corporate presentation, which now incorporates preliminary data from the GBM AGILE Phase II/III clinical trial evaluating paxalisib versus the standard of care for the treatment of in patients with glioblastoma. The updated presentation can be found at <https://www.kaziatherapeutics.com/site/pdf/ebcc5b2e-29a6-410c-ab9a-c3e722413615/Kazia-Corporate-Presentation-November-2024.pdf>

### **Participation in Upcoming and Recent Medical and Investor Conferences**

The company plans on attending the following medical conferences in the fourth quarter of 2024:

- Society for Neuro-Oncology 29<sup>th</sup> Annual Meeting and Education Day, November 21-24, 2024, in Houston, TX
- San Antonio Breast Cancer Symposium, December 10-13, 2024, in San Antonio, TX

These events provide Kazia with the opportunity to engage with key stakeholders and share the Company’s vision to make a difference in the lives of patients by developing innovative cancer



treatments. Kazia looks forward to meeting with investors in person at these events and invites discussion regarding partnering and investment opportunities.

Over the last several months, the Company has also participated and presented at a number of medical and investor conferences, including:

- H C Wainwright 26th Annual Global Investment Conference from Sep. 9-11, 2024
- 15th Biennial AACR Ovarian Cancer Research Symposium, Sep. 20 – 21, 2024
- Oppenheimer Oncology Summit, in collaboration with MD Anderson Cancer Center, Sep. 26, 2024
- American Society for Radiation Oncology Annual Meeting, Sep. 29 – Oct. 1, 2024
- Deerfield CEO Conference, Oct. 8-9, 2024
- Maxim Group's 2024 Healthcare Virtual Summit, Fireside Chat, Oct. 15, 2024

### **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 study in glioblastoma reported early signals of clinical activity in 2021, and a pivotal study in glioblastoma, GBM AGILE, has been completed with presentation of paxalisib arm data expected later in 2024 at a major medical conference. 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](http://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 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.

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