

ASX RELEASE

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## GBM AGILE OPENS TO PAXALISIB IN EUROPE

**Sydney, 31 May 2022** – Kazia Therapeutics Limited (NASDAQ: KZIA; ASX: KZA), an oncology-focused drug development company, is pleased to announce that the GBM AGILE study in glioblastoma (NCT03970447) has opened recruitment to the paxalisib arm in Europe.

University Hospital Zurich in Zurich, Switzerland, under the leadership of principal investigator and regional principal investigator of Europe, Dr Michael Weller, will join over 40 sites in the US and Canada that are currently recruiting to the paxalisib arm. This represents the first time that paxalisib has been the subject of clinical trial activity in Switzerland. Additional sites are expected to open in Switzerland, and in several other European countries, in the near future.

### Key Points

- GBM AGILE is a multi-drug platform study, designed to identify promising new therapies for glioblastoma. It is sponsored by the Global Coalition for Adaptive Research (GCAR) and three drug candidates are currently participating: Bayer's regorafenib, Kazia's paxalisib, VAL-083 from Kintara Therapeutics. Two additional drug candidates will be starting in 2Q CY2022; Troriluzole from Biohaven Pharmaceuticals, and VT1021 from Vigeo Therapeutics.
- The first US site opened to the paxalisib arm in January 2021, and the first Canadian site in November 2021. At present, over 40 sites are recruiting to the paxalisib arm.
- University Hospital Zurich in Zurich, Switzerland, is the first European site to commence recruitment to the paxalisib arm, with additional sites in Switzerland and in several other European countries expected to come online during 1H CY2022.
- Expansion of GBM AGILE to China is anticipated in 2Q or 3Q CY2022.

Dr Michael Weller, Director of the Department of Neurology at University Hospital Zurich, commented, "We are very pleased to see the ongoing expansion in Europe of this very innovative clinical trial. There is a profound need for new treatment options in glioblastoma, and GBM AGILE has been designed to evaluate new therapies in the most efficient way possible. We look forward to making a significant contribution to the study, and to seeing results in due course."

### Board of Directors

**Mr Iain Ross** Chairman, Non-Executive Director

**Mr Bryce Carmine** Non-Executive Director

**Mr Steven Coffey** Non-Executive Director

**Dr James Garner** Chief Executive Officer, Managing Director

## **GBM AGILE**

The paxalisib arm of GBM AGILE is recruiting two groups of patients: newly diagnosed patients with the unmethylated MGMT promotor, a genetic marker that denotes near-total resistance to temozolomide, the existing FDA-approved standard of care, and recurrent patients who have progressed despite treatment with temozolomide. The paxalisib arm commenced recruitment in the United States in January 2021 and in Canada in November 2021.

The primary endpoint of GBM AGILE is overall survival, which is considered the gold standard for the evaluation of new cancer therapies, and which is the preferred approval endpoint for regulators such as the US FDA. Kazia expects GBM AGILE to serve as the pivotal study for registration in key markets, including in the European Union.

Patients recruited to the paxalisib arm will be compared against a shared control group. The duration of paxalisib's enrolment is initially estimated to be approximately 30-36 months, and final data is provisionally anticipated by the end of CY2023.

### **For More Information, Please Contact:-**

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### **About Kazia Therapeutics Limited**

Kazia Therapeutics Limited (NASDAQ: KZIA; ASX: KZA) is an oncology-focused drug development company, based in Sydney, Australia.

Our lead program is paxalisib, a brain-penetrant inhibitor of the PI3K / Akt / mTOR pathway, which is being developed to treat glioblastoma, the most common and most aggressive form of primary brain cancer in adults. Licensed from Genentech in late 2016, paxalisib commenced recruitment to GBM AGILE, a pivotal study in glioblastoma, in January 2021. Seven additional studies are active in various forms of brain cancer. Paxalisib was granted Orphan Drug Designation for glioblastoma by the US FDA in February 2018, and Fast Track Designation for glioblastoma by the US FDA in August 2020. In addition, paxalisib was

granted Rare Pediatric Disease Designation and Orphan Designation by the US FDA for DIPG in August 2020.

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 compelling evidence of synergy with immunology agents. A phase I study commenced recruitment in November 2021.

For more information, please visit [www.kaziatherapeutics.com](http://www.kaziatherapeutics.com) or follow us on Twitter @KaziaTx.

This document was authorized for release to the ASX by James Garner, Chief Executive Officer, Managing Director.