ASX RELEASE

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# GBM AGILE OPENS TO PAXALISIB IN CANADA

**Sydney, 29 November 2021** – Kazia Therapeutics Limited (ASX: KZA; NASDAQ: KZIA), an oncology-focused drug development company, is pleased to inform stakeholders that the GBM AGILE study in glioblastoma (NCT03970447) has opened at Sunnybrook Health Sciences Centre in Toronto, Ontario. This marks the first Canadian site to open to paxalisib, and the first opportunity for Canadian patients to access the drug.

Sunnybrook Health Sciences Centre, under the leadership of principal investigator, Dr James Perry, will join more than two dozen US sites currently recruiting to the paxalisib arm. Three further sites in Canada are presently working through the administrative requirements to open to paxalisib and are expected to do so in coming weeks.

**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, and VAL-083 from Kintara Therapeutics.
- The first US site opened to the paxalisib arm in January 2021. At present, more than two dozen US sites are recruiting to the paxalisib arm.
- Sunnybrook Health Sciences Centre is the first Canadian site to commence recruitment to the paxalisib arm, with several additional sites in Canada expected to come online during CY2021.
- Expansion of GBM AGILE to Europe and China is anticipated over coming months.

Dr James Perry, Professor of Medicine at the University of Toronto, Principal Investigator at Sunnybrook Health Sciences Centre, and Lead Investigator for GBM AGILE in Canada, commented, "We are delighted to see the study open new arms in Canada. At least 1,200 Canadians are diagnosed with glioblastoma each year, and the need for new treatment options has never been more acute. My colleagues and I have been working closely with the Global Coalition for Adaptive Research to bring this exciting and innovative study to Canadian patients."

**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 January 2021 and has been recruiting solely in the United States since that time. The opening of McGill University to the paxalisib arm represents the commencement of clinical trial activity for paxalisib in Canada.

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 Canada.

The study will recruit up to 200 patients on paxalisib in total, and these will be compared against a shared control group. The total data set for paxalisib will therefore likely include up to approximately 450 patients from GBM AGILE. The duration of paxalisib's enrolment is initially estimated to be approximately 30-36 months.

**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. Eight additional studies are active in other 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 immuno-oncology agents. A phase I study opened to recruitment in November 2021.

For more information, please visit 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.

**About Sunnybrook**

Sunnybrook Health Sciences Centre is inventing the future of health care for the 1.3 million patients the hospital cares for each year, through the dedication of its more than 10,000 staff and volunteers.

An internationally recognized leader in research and education, a full affiliation with the University of Toronto distinguishes Sunnybrook as one of Canada's premier academic health sciences centres. Sunnybrook specializes in caring for high-risk pregnancies, critically ill newborns and adults, offering specialized rehabilitation, and treating and preventing cancer, cardiovascular disease, neurological and psychiatric disorders, orthopaedic and arthritic conditions, and traumatic injuries. The hospital also has a unique and national leading program for the care of Canada's war veterans.