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Global Coalition for Adaptive Research, Kazia, and Kintara Announce Commencement of Kazia's Paxalisib and Kintara's VAL-083 in GBM AGILE Trial

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KAZIA AND KINTARA NOW ENROLLING IN GBM AGILE, REGISTRATIONAL PHASE 2-3 ADAPTIVE PLATFORM TRIAL TO EVALUATE INTERVENTIONS FOR PATIENTS WITH GLIOBLASTOMA

KAZIA'S PAXALISIB AND KINTARA'S VAL-083 TO BE EVALUATED ACROSS MULTIPLE INTERNATIONAL TRIAL SITES

KINTARA'S VAL-083 WILL BE THE FIRST INVESTIGATIONAL DRUG TO ALSO BE TESTED IN GBM AGILE FOR MGMT METHYLATED TUMORS

LOS ANGELES – (BUSINESS WIRE)--Global Coalition for Adaptive Research (LOS ANGELES, CA), Kazia Therapeutics Limited (ASX: KZA, NASDAQ: KZIA, SYDNEY, Australia), and Kintara Therapeutics, Inc. (NASDAQ: KTRA, SAN DIEGO, CA) -- The Global Coalition for Adaptive Research (GCAR) in collaboration with Kazia and Kintara, today announced the activation of Kazia's *paxalisib* and Kintara's *VAL-083* in GBM AGILE (Glioblastoma Adaptive Global Innovative Learning Environment). GBM AGILE is a revolutionary patient-centered, adaptive platform trial for registration that tests multiple therapies for patients with newly-diagnosed and recurrent glioblastoma (GBM) – the deadliest form of brain cancer.

Kazia's *paxalisib* and Kintara's *VAL-083* are entering the GBM AGILE trial, which initially opened in July 2019 and has screened over 370 patients to date.

Kazia's *paxalisib* will be enrolling in newly-diagnosed unmethylated (NDUM) and recurrent GBM and Dr. Ingo Mellinghoff, Chair of the Department of Neurology at Memorial Sloan Kettering Cancer Center and Dr. Eudocia Q Lee, Director of Clinical Research at the Center for Neuro-Oncology at Dana-Farber and an Assistant Professor of neurology at Harvard Medical School are serving as arm Principal Investigators for the paxalisib arm.

Kintara's *VAL-083* will be enrolling in NDUM and recurrent GBM as well as be the first

compound being evaluated for patients with newly-diagnosed methylated MGMT. *VAL-083* will be led by arm Principal Investigators, Dr. John de Groot, Professor, Department of Neuro-Oncology, MD Anderson Cancer Center, and Dr. James Perry, Professor of Neurology at the University of Toronto and Sunnybrook Research Institute.

“GBM AGILE is an innovative clinical trial approach that enables us to simultaneously and dynamically study the effects of multiple new drug candidates. With the inclusion of *paxalisib* and *VAL-083* for NDUM and recurrent GBM patients, as well as *VAL-083* for the additional methylated GBM patient group, we are excited to offer all GBM patients access to these latest therapies,” says Dr. James Perry. “Both investigational drugs have the potential to support improved outcomes for GBM patients, who need new treatment options.”

Dr. Ingo Mellinghoff, who also serves as co-Chair of the GBM AGILE Arm Identification and Selection Committee adds, “GBM AGILE is a transformative effort in our field, designed to provide glioblastoma patients in many different countries access to the latest, most personalized therapies and, at the same time, rigorously evaluate the activity of these therapies in an optimized learning environment. *Paxalisib* and *VAL-083* are two important steps in this direction and offer potentially beneficial treatments to our patients, who deserve new and better options for their care.”

GBM AGILE is an international, innovative platform trial designed to more rapidly identify and confirm effective therapies for patients with glioblastoma through response adaptive randomization and a seamless phase 2/3 design. The trial, conceived by over 130 key opinion leaders, is conducted under a master protocol, allowing multiple therapies or combinations of therapies from different pharmaceutical partners to be evaluated simultaneously. With its innovative design and efficient operational infrastructure, data from GBM AGILE can be used as the foundation for a new drug application (NDA) and biologics license application (BLA) submissions and registrations to the FDA and other health authorities.

The new interventions are opening first at Henry Ford Cancer Institute in Detroit under Henry Ford site Principal Investigator, Dr. Tom Mikkelsen, Medical Director, Henry Ford Precision Medicine Program & Clinical Trials, and will subsequently open at over 30 trial sites across the United States with additional global sites in Canada, Europe, and China to follow.

"We were first in the world to enroll a patient in the GBM AGILE study, which is designed to help us quickly identify the most effective therapies for patients with glioblastoma," notes Dr. Tom Mikkelsen. "We are excited about the potentially improved treatments afforded to our patients in this study with the additional options of *paxalisib* and *VAL-083.*"

Kazia’s *paxalisib* (formerly GDC-0084) is a small molecule inhibitor of the PI3K / AKT / mTOR pathway. The PI3K pathway appears to be disordered in more than 85% of cases of glioblastoma, making this pathway a high-potential target for new glioblastoma therapies. *Paxalisib* is a potent inhibitor of the PI3K pathway, and has been shown to have an anti-tumor effect in animal models of glioblastoma. Licensed from Genentech in late 2016, *paxalisib* is distinguished by its ability to cross the so-called blood-brain barrier, which prevents many drugs from fully affecting brain tissue. Seven 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.

“We are proud to be joining GBM AGILE. This is an important and innovative effort, utilizing a platform approach and cutting-edge adaptive design to rapidly identify whether drugs such as *paxalisib* can bring benefit to patients with glioblastoma,” said Dr. James Garner, Chief Executive Officer, Kazia. “There is a profound need for new therapeutic options in this disease, and GBM AGILE has been designed to accelerate the process of making new drugs available to patients and clinicians. We have seen encouraging data with *paxalisib* in earlier clinical studies, so we hope that success in GBM AGILE may pave the way to providing a new treatment in this disease.”

Kintara’s *VAL-083* is a "first-in-class," small molecule bifunctional alkylating agent that crosses the blood-brain barrier. *VAL-083* is independent of the MGMT resistance mechanism and has been assessed in over 40 Phase 1 and Phase 2 clinical trials in multiple indications sponsored by the U.S. National Cancer Institute (NCI). Published pre-clinical and clinical data indicate that *VAL-083* has activity against a range of tumor types, including lung, brain, cervical, ovarian tumors and hematologic (blood) cancers. *VAL-083* has been granted Orphan Drug Designation for GBM by the FDA and EMA and has also been granted Orphan Drug Designations for medulloblastoma and ovarian cancer from the FDA. In addition, the FDA granted Fast Track Designation for *VAL-083* in recurrent GBM. *VAL-083* is approved as a cancer chemotherapeutic in China for the treatment of chronic myelogenous leukemia and lung cancer. *VAL-083* has not been approved for any indications outside of China.

“Kintara is pleased to participate in the groundbreaking GBM AGILE trial, and is excited to be the first investigational drug selected for newly-diagnosed methylated GBM in the study. With *VAL-083* being evaluated in all subtypes we expect that this study will generate important insights into *VAL-083’s* potential to improve health outcomes for all GBM patients,” said Saiid Zarrabian, Kintara’s Chief Executive Officer.

About Global Coalition for Adaptive Research (GCAR)

The Global Coalition for Adaptive Research (GCAR) is a 501(c)(3) nonprofit organization uniting physicians, clinical researchers, advocacy and philanthropic organizations, biopharma, health authorities, and other key stakeholders in healthcare to expedite the discovery and development of treatments for patients with rare and deadly diseases by serving as sponsor of innovative and complex trials including master protocols and platform trials. GCAR is the sponsor of GBM AGILE, an adaptive platform trial for patients with GBM – the most common and deadliest of malignant primary brain tumors. Key strategic partners for the GBM AGILE trial effort include the National Brain Tumor Society, National Foundation for Cancer Research, and Asian Fund for Cancer Research, three nonprofit organizations that are working together to provide philanthropic support as well as assistance in communicating with patients and families and inviting all others to join in supporting this innovating approach to brain tumor treatment development.

To learn more about GCAR, visit www.gcaresearch.org and follow us: @GCAResearch and www.facebook.com/GCAResearch.

About Kazia Therapeutics Limited

Kazia Therapeutics Limited (ASX: KZA, NASDAQ: KZIA) is an innovative oncology-focused biotechnology company, based in Sydney, Australia. Our pipeline includes two clinical-stage drug development candidates, and we are working to develop therapies across a range of oncology indications.

Our lead program is *paxalisib* (formerly GDC-0084), a small molecule 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* entered GBM AGILE, a pivotal study in glioblastoma, in October 2020. 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.

For more information, please visit www.kaziatherapeutics.com.

About Kintara

Located in San Diego, California, Kintara (Nasdaq: KTRA) is dedicated to the development of novel cancer therapies for patients with rare unmet medical needs. Kintara is currently developing two Phase 3-ready therapeutics, *VAL-083* for GBM and *REM-001* for cutaneous metastatic breast cancer (CMBC).

VAL-083 is a "first-in-class," small-molecule chemotherapeutic with a novel mechanism of action that has demonstrated clinical activity against a range of cancers, including central nervous system, ovarian and other solid tumors (e.g. NSCLC, bladder cancer, head and neck) in U.S. clinical trials sponsored by the NCI. Based on Kintara's internal research programs and these prior NCI-sponsored clinical studies, Kintara is currently conducting clinical trials to support the development and commercialization of *VAL-083* in GBM.

REM-001 is a proprietary, late-stage photodynamic therapy platform that holds promise as a localized cutaneous, or visceral, tumor treatment as well as in other potential indications. *REM-001* therapy, has been previously studied in four Phase 2/3 clinical trials in patients with CMBC, who had previously received chemotherapy and/or failed radiation therapy. With clinical efficacy of 80% complete responses of evaluable CMBC lesions and an existing robust safety database of approximately 1,100 patients across multiple indications, Kintara is advancing the *REM-001* CMBC program to late-stage pivotal testing.

For more information, please visit www.kintara.com.

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