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Kintara Therapeutics Provides Positive Site Activation Update on GCAR Phase 2/3 Clinical Trial for Glioblastoma

SAN DIEGO, Aug. 17, 2021 /PRNewswire/ -- [Kintara Therapeutics, Inc.](#) (Nasdaq: KTRA) ("Kintara" or the "Company"), a biopharmaceutical company focused on the development of new solid tumor cancer therapies, today announced that the VAL-083 treatment arm in the Global Coalition for Adaptive Research (GCAR) registrational Phase 2/3 clinical trial for glioblastoma multiforme (GBM) has been activated in 26 U.S. sites as of August 16, 2021.

The trial, titled GBM AGILE (Glioblastoma Adaptive Global Innovative Learning Environment), is a patient-centered, Phase 2/3 adaptive platform trial evaluating multiple therapies for patients with newly-diagnosed and recurrent GBM. Since January 2021, GCAR has accelerated the pace of clinical site activation with increased awareness in the medical community of Kintara's arm of the study. GCAR plans to enroll 150-200 patients in the Kintara arm of the study at over 40 sites in the U.S. and Canada with potential to increase this total to 65 clinical trial centers worldwide.

"The entire Kintara team remains enthused by the pace at which our treatment arm is being activated in the study," commented Saiid Zarrabian, Kintara's Chief Executive Officer. "With 26 sites already active, including the recent addition of prestigious centers such as the Dana Farber Cancer Institute and Massachusetts General Hospital, we are delighted to witness GCAR's exceptional clinical trial execution capabilities that drew us to participate in this exciting and highly efficient registrational study."

Key GBM AGILE Highlights for VAL-083

- Only therapeutic agent currently being evaluated in all three GBM patient subtypes: newly-diagnosed methylated MGMT; newly-diagnosed unmethylated MGMT; and recurrent
- May accelerate VAL-083's time to pivotal trial completion and potential regulatory submission by up to 18 months
- Cost-effective opportunity to advance VAL-083 due to the GBM AGILE study's expense sharing protocol

GBM AGILE is an international, innovative platform trial designed to more rapidly identify and confirm effective therapies for patients with GBM 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 may be used as the

foundation for a new drug application and biologics license application submissions and registrations to the FDA and other health authorities.

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). 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.

Published pre-clinical and clinical data indicate that VAL-083 has activity against a range of tumor types, including lung, brain, cervical, and ovarian tumors as well as 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 by 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.

ABOUT KINTARA

Located in San Diego, California, Kintara is dedicated to the development of novel cancer therapies for patients with unmet medical needs. Kintara is developing two late-stage, Phase 3-ready therapeutics for clear unmet medical needs with reduced risk development programs. The two programs are VAL-083 for GBM and REM-001 for cutaneous metastatic breast cancer (CMBC).

Kintara's 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 to date of 80% complete responses of CMBC evaluable lesions, and with 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.

SAFE HARBOR STATEMENT

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995, including statements regarding the status of the Company's clinical trials and the GBM AGILE study. Any forward-looking statements contained herein are based on current expectations but are subject to a number of risks and uncertainties. The factors that could cause actual future results to differ materially from current expectations include, but are not limited to, risks and uncertainties relating to the impact of the COVID-19 pandemic on the Company's operations and clinical trials; the Company's ability to develop, market and sell products based on its technology; the expected benefits and efficacy of the Company's products and technology; the availability of substantial additional funding for the Company to continue its operations and to conduct research and

development, clinical studies and future product commercialization; and, the Company's business, research, product development, regulatory approval, marketing and distribution plans and strategies. These and other factors are identified and described in more detail in the Company's filings with the SEC, including the Company's Annual Report on Form 10-K for the year ended June 30, 2020, the Company's Quarterly Reports on Form 10-Q, and the Company's Current Reports on Form 8-K.

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