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Kintara Therapeutics Enrolls Final Patient in Phase 2 Clinical Trial of VAL-083 for Adjuvant Treatment of Brain Tumors

SAN DIEGO, June 3, 2021 /PRNewswire/ -- [Kintara Therapeutics, Inc.](https://www.kintara.com) (Nasdaq: KTRA) ("Kintara" or the "Company"), a biopharmaceutical company focused on the development of new solid tumor cancer therapies, today announced it has enrolled the final patient in the adjuvant arm of its ongoing Phase 2 clinical study of VAL-083 being conducted at the MD Anderson Cancer Center (MD Anderson). The adjuvant arm of the study investigates newly-diagnosed patients suffering from glioblastoma multiforme (GBM) receiving VAL-083 in place of standard of care temozolomide (TMZ) as adjuvant therapy following surgery and chemoradiation TMZ. The trial was designed to enroll up to 36 patients to determine whether treatment with VAL-083 improves overall survival.

The Phase 2 trial is an open-label, two-arm, biomarker-driven study testing VAL-083 in GBM patients who have an unmethylated promoter of the methylguanine DNA-methyltransferase (MGMT) gene. Efficacy is being measured based on overall survival and progression-free survival. In February 2021, the Company announced the trial's second arm (recurrent GBM) enrolled its final patient.

"Enrolling the final patient in the adjuvant arm of the Phase 2 study at MD Anderson is yet another important milestone for the Company as we continue to advance VAL-083 in multiple settings including the GCAR sponsored GBM AGILE study where we have already initiated patient recruitment at 15 sites as the only therapeutic agent currently being evaluated in this adaptive design registration study for all three GBM patient subtypes; newly-diagnosed methylated MGMT, newly-diagnosed unmethylated MGMT, and recurrent," commented Saïd Zarrabian, Kintara's Chief Executive Officer.

VAL-083 is a 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). 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 has 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 (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 CMBC evaluable 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 or follow us on Twitter at [@Kintara_Thera](https://twitter.com/Kintara_Thera), [Facebook](https://www.facebook.com/Kintara_Thera) and [Linkedin](https://www.linkedin.com/company/kintara-thera).

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.

CONTACTS

Investors
CORE IR
516-222-2560
ir@coreir.com

Media
Jules Abraham
Director of Public Relations
CORE IR
917-885-7378

julesa@coreir.com

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