September 22, 2021

Kintara Reports Topline Results from Phase 2 Clinical Study of VAL-083 as Adjuvant Therapy for Newly-Diagnosed GBM Patients

SAN DIEGO, Sept. 22, 2021 /PRNewswire/ --Kintara Therapeutics, Inc. (Nasdaq: KTRA) ("Kintara" or the "Company"), a biopharmaceutical company developing novel cancer therapies for patients who are failing, or are resistant to, current treatment regimens today announced topline data results from the newly-diagnosed adjuvant arm of its open-label, Phase 2 clinical study being conducted at the MD Anderson Cancer Center (MD Anderson) in Houston, Texas.

The Phase 2 trial was a two-arm, biomarker-driven study testing VAL-083 in glioblastoma multiforme (GBM) patients who have an unmethylated promoter of the methylguanine DNA-methyltransferase (MGMT) gene. The Company previously announced (July 2021) topline data results from the recurrent GBM arm of the study which provided important safety and efficacy data to support the continued evaluation of VAL-083 as a treatment option for GBM.

The newly-diagnosed adjuvant arm of the study addressed GBM patients requiring adjuvant therapy after chemoradiation with temozolomide. The trial arm enrolled 39 patients (36 efficacy evaluable) initially receiving a dose of 30 mg/m^2/day on days 1, 2 and 3 of a 21-day cycle.

Summary of results:

- Progression Free Survival (PFS) for the 36 efficacy evaluable patients is 10.0 months (95% Confidence Interval (CI) 8.2-10.8 months). While this is not a head-to-head trial, historical data for this patient population has demonstrated PFS of 5.3-6.9 months*.
- Median overall survival (mOS) for the 36 efficacy evaluable patients is 16.5 months (CI 13.3-19.3 months). While this is not a head-to-head trial historical data for this patient subpopulation has demonstrated mOS of 12.7-16.0 months*.
- Consistent with prior studies, myelosuppression was the most common adverse event. One patient experienced a serious adverse event (SAE) possibly related to VAL-083.

The dosing regimen (30 mg/m^2/day) of the MD Anderson study mirrors the trial design of the newly-diagnosed adjuvant study arm of the GBM AGILE study. GBM AGILE, which is sponsored by the Global Coalition for Adaptive Research (GCAR), is a revolutionary, patient-centered, registrational, seamless Phase 2/3 adaptive platform trial evaluating multiple therapies for patients with newly-diagnosed and recurrent GBM. VAL-083 currently represents the only therapeutic agent being evaluated in all three GBM patient subtypes: methylated MGMT, newly-diagnosed unmethylated MGMT, and recurrent.

"On behalf of the entire Kintara team, I wish to extend gratitude to MD Anderson, and all of the patients who participated in both arms of the trial," said Saiid Zarrabian, Kintara's Chief Executive Officer. "The topline results from the newly-diagnosed adjuvant arm are a particularly important milestone for the company as it further affirms the efficacy and safety data reported this past July from the recurrent arm, thus providing additional support and momentum to continue the evaluation of VAL-083 for the treatment of GBM."

Dr. Barbara O'Brien, the Principal Investigator for the Phase 2 study at MD Anderson added, "I continue to be impressed by the clinical data generated by both arms of the study and remain excited by VAL-083's potential to be a game-changing therapeutic agent to help patients suffering from this deadly disease."

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 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.

** Hegi et al N Eng J Med 352; 997-1003 (2005);*
Tanguturi et al. NeuroOncol. 19(7): 908-917 (2017)

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, bifunctional alkylating agent that crosses the blood-brain-barrier and has 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, Facebook and Linkedin.

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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