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Kintara Reports Topline Results From Phase 2 Clinical Trial of VAL-083 for Recurrent GBM

SAN DIEGO, July 1, 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 recurrent arm of its open-label, Phase 2 clinical study of its lead compound VAL-083 being conducted at the MD Anderson Cancer Center (MD Anderson) in Houston, Texas.

The Phase 2 trial is 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 recurrent arm of the study addressed patients who have been pre-treated with temozolomide prior to disease recurrence.

The recurrent arm of the trial enrolled 89 patients, with 35 patients (35 efficacy evaluable) initially receiving a dose of VAL-083 at 40 mg/m^2/day, and 54 patients (48 efficacy evaluable) initially receiving the treatment dose of 30 mg/m^2/day on days 1, 2 and 3 of a 21-day cycle. This 30 mg dose corresponds to the dose being studied in the recently initiated and currently enrolling VAL-083 study arm of the GBM AGILE study.

Summary of results:

- Median overall survival (mOS) for the 48 efficacy evaluable patients initially receiving the treatment dose of 30 mg/m2/day is 8.0 months (95% confidence interval: CI 5.9-9.9 months). While this is not a head-to-head trial, historically, lomustine, which is the most commonly used chemotherapy for these patients, has demonstrated mOS of 7.2 months*

- Consistent with prior studies, myelosuppression was the most common adverse event. In the 30 mg/m2/day starting dose cohort, five patients experienced a serious adverse event (SAE) possibly related to VAL-083

- For the 83 efficacy evaluable patients who have completed at least one cycle of treatment mOS was 7.5 months (CI 6.1-9.0 months)

"I'm extremely pleased with the outcome of the recurrent arm of the study as it provided important safety and efficacy data to support further evaluation of VAL-083 for the treatment of GBM," said Saiid Zarrabian, Kintara's Chief Executive Officer. "The study of VAL-083 continues in GBM AGILE, an adaptive registration study where it is currently the only therapeutic agent being evaluated for all three GBM patient subtypes: newly-diagnosed methylated MGMT, newly-diagnosed unmethylated MGMT, and recurrent."

Dr. Barbara O'Brien, the Principal Investigator for the Phase 2 study at MD Anderson added, "These data continue to support VAL-083's compelling potential as a potent DNA targeting cytotoxic agent for the treatment of GBM, which remains a deadly disease with an urgent need for improved treatment options."

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, and 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.

** Wick et al N.Eng.J.Med . 377:1954 1963 (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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