June 15, 2022

Kintara Therapeutics Granted Fast Track Designation from the FDA for VAL-083 for Newly-Diagnosed Glioblastoma

SAN DIEGO, June 15, 2022 /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 United States Food and Drug Administration (FDA) has granted Fast Track Designation (FTD) to Kintara's VAL-083 for the treatment of patients with newly-diagnosed unmethylated glioblastoma (GBM).

Fast Track is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. Some of the significant benefits of FTD include:

- Enhanced access to the FDA, including opportunities for more frequent meetings and written consultation throughout the remaining development of VAL-083.
- Drugs with FTD are eligible to apply for Accelerated Approval and Priority Review at the time of a New Drug Application (NDA) submission, which may result in faster product approval.
- FTD also allows for 'rolling review', whereby Kintara may submit completed sections of the VAL-083 NDA as they become available, rather than at the end of development.

"We believe Fast Track Designation is indicative of VAL-083's potential to improve outcomes for patients with GBM, the most aggressive form of brain cancer," stated Robert E. Hoffman, President and CEO of Kintara. "We look forward to announcing top-line data from the international registrational phase 2/3 GBM AGILE Study around the end of calendar year 2023. Fast Track Designation allows us to work closely with the FDA and may expedite our commercial launch of VAL-083, if approved."

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).

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 National Cancer Institute (NCI). Based on Kintara's internal research programs and these prior NCI-sponsored clinical studies, Kintara

is currently advancing VAL-083 in the Global Coalition for Adaptive Research registrational phase 2/3 clinical trial titled Glioblastoma Adaptive Global Innovative Learning Environment (GBM AGILE) Study to support the development and commercialization of VAL-083 in GBM.

Kintara is also advancing its 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.

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 impact of Fast Track Designation and 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, 2021, 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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