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Kintara Therapeutics Receives Study May Proceed Letter from the FDA for REM-001 for Cutaneous Metastatic Breast Cancer

SAN DIEGO, Aug. 9, 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 it has received a Study May Proceed letter from the United States Food and Drug Administration (FDA) to begin its 15 patient study evaluating REM-001 Photodynamic Therapy (PDT) for the treatment of Cutaneous Metastatic Breast Cancer (CMBC). This study is intended to aid in the design of a planned phase 3 registrational study.

"The FDA's reactivation of our Investigational New Drug application for REM-001 is an important milestone for Kintara," stated Robert E. Hoffman, President and CEO of Kintara. "This clinical study is part of a broad strategy designed to demonstrate proof of concept for our Photodynamic Therapy platform in CMBC, an area of unmet medical need, as well as across other cutaneous metastatic cancers."

PDT is a treatment that uses light sensitive compounds, or photosensitizers, that, when exposed to specific wavelengths of light, act as a catalyst to produce a form of oxygen that induces local tumor cell death. The planned clinical study is expected to enroll 15 patients with CMBC that is refractory or not eligible for radiotherapy or surgery. The study will evaluate cutaneous tumor response using standardized and calibrated 3D digital photography.

"We're excited to further explore the potential benefits of this second-generation photosensitizer, particularly given the unmet need of CMBC," added Dr. Mario E. Lacouture, Professor and Director of the Oncodermatology Program in the Dermatology Service Department of Medicine at Memorial Sloan Kettering Cancer Center and Chairman of Kintara's REM-001 Scientific Advisory Board.

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 glioblastoma (GBM) and REM-001 for 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 PDT 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 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.

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