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Kintara Therapeutics Receives Orphan Drug Designation for VAL-083 for Treatment of Diffuse Intrinsic Pontine Glioma (DIPG)

SAN DIEGO, Dec. 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 it has received Orphan Drug Designation (ODD) from the U.S. Food and Drug Administration (FDA) for VAL-083 for the treatment of diffuse intrinsic pontine glioma (DIPG), a rare and highly-aggressive childhood brain cancer.

The FDA's ODD program provides orphan status to drugs defined as those intended for the treatment, diagnosis or prevention of rare diseases that affect fewer than 200,000 people. ODD provides the sponsor of the drug with development incentives, including tax credits for qualified clinical testing, prescription drug user fee exemptions and seven-year marketing exclusivity upon FDA approval.

"This is another important step for us in evaluating VAL-083 as a treatment for brain tumors in addition to our lead indication of glioblastoma," said Robert E. Hoffman, Kintara's President and CEO. "We will continue with our clinical advancement of the drug candidate with our objective of delivering a much-needed new treatment that can benefit patients."

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 Therapy 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 also has 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, which consists of the laser light source, the light delivery device, and the REM-001 drug product, 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. In CMBC, REM-001 has a clinical efficacy to date of 80% complete responses of CMBC evaluable lesions and an existing robust safety database of approximately 1,100 patients across multiple indications. Kintara has paused the REM-001 CMBC program to conserve cash resources.

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, 2022, the Company's Quarterly Reports on Form 10-Q, and the Company's Current Reports on Form 8-K.

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