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Kintara Announces Initiation of Patient Recruitment for VAL-083's Study Arm in the GBM AGILE Trial

SAN DIEGO, Jan. 13, 2021 /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 patient recruitment has commenced in the Global Coalition for Adaptive Research (GCAR) registrational Phase 2/3 clinical trial for glioblastoma (GBM). The trial, titled GBM AGILE (Glioblastoma Adaptive Global Innovative Learning Environment), is a revolutionary, patient-centered, adaptive platform trial for registration evaluating multiple therapies for patients with newly-diagnosed and recurrent GBM.

Key GBM AGILE Highlights for VAL-083

- Only therapeutic agent currently being evaluated in all three GBM patient subtypes: newly-diagnosed methylated MGMT; newly-diagnosed unmethylated MGMT; and recurrent
- May accelerate VAL-083's time to pivotal trial completion and potential regulatory submission by up to 18 months
- Cost-effective opportunity to advance VAL-083 due to the GBM AGILE study's expense sharing protocol
- Anticipating rapid enrollment, targeting 150-200 patients with 34 active and recruiting U.S. sites with plans to increase to 40 sites during Q1, 2021, including Canada and other international locations to follow

"The entire Kintara team is grateful and excited to participate in GCAR's groundbreaking GBM AGILE study as it offers an extraordinary opportunity to facilitate the advancement of VAL-083's clinical development in a premier GBM study," commented Saiid Zarrabian, Kintara's Chief Executive Officer. "This is truly an important milestone for Kintara as we believe the study will generate important insights into the breadth of VAL-083's potential to address this deadliest form of brain cancer in all patient subtypes, while potentially bringing the program to the doorstep of commercialization."

GBM AGILE is an international, innovative platform trial designed to more rapidly identify and confirm effective therapies for patients with glioblastoma through response adaptive randomization and a seamless Phase 2/3 design. The trial, conceived by over 130 key opinion leaders, is conducted under a master protocol allowing multiple therapies or combinations of therapies from different pharmaceutical partners to be evaluated simultaneously. With its innovative design and efficient operational infrastructure, data from GBM AGILE can be used as the foundation for a new drug application and biologics license application submissions and registrations to the FDA and other health authorities.

Kintara's VAL-083 is a "first-in-class," small molecule bifunctional alkylating agent that crosses the blood-brain barrier. 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 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.

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 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 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.

About Global Coalition for Adaptive Research (GCAR)

The Global Coalition for Adaptive Research (GCAR) is a 501(c)(3) nonprofit organization uniting physicians, clinical researchers, advocacy and philanthropic organizations, biopharma, health authorities, and other key stakeholders in healthcare to expedite the discovery and development of treatments for patients with rare and deadly diseases by serving as sponsor of innovative and complex trials including master protocols and platform trials. GCAR is the sponsor of GBM AGILE, an adaptive platform trial for patients with GBM – the most common and deadliest of malignant primary brain tumors. Key strategic partners for the GBM AGILE trial effort include the National Brain Tumor Society, National Foundation for Cancer Research, and Asian Fund for Cancer Research, three nonprofit organizations that are working together to provide philanthropic support as well as assistance in communicating with patients and families and inviting all others to join in

supporting this innovating approach to brain tumor treatment development.

To learn more about GCAR, visit www.gcaresearch.org.

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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KINTARA Therapeutics

View original content to download multimedia:http://www.prnewswire.com/news-releases/kintara-announces-initiation-of-patient-recruitment-for-val-083s-study-arm-in-the-gbm-agile-trial-301207295.html

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