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Kintara Presents Updates on Two Phase 2 Clinical Trials at the 2021 American Association for Cancer Research Annual Meeting

SAN DIEGO, April 12, 2021 /PRNewswire/ -- [Kintara Therapeutics, Inc.](#) (Nasdaq: KTRA) ("Kintara" or the "Company"), a biopharmaceutical company developing novel cancer therapies for patients who are failing, or resistant to, current treatment regimens, today announced interim data results from two Phase 2 clinical trials evaluating VAL-083, the Company's lead compound, for the treatment of glioblastoma multiforme (GBM). The data were presented in two posters at the 2021 American Association for Cancer Research (AACR) Annual Meeting, which is taking place virtually from April 10-15, 2021.

Poster CT238 provides an update from two patient groups receiving VAL-083 in an open-label, Phase 2 study in recurrent and adjuvant unmethylated GBM settings being conducted at the MD Anderson Cancer Center in Houston, Texas. The second poster, CT172, updates the open-label, Phase 2 study of VAL-083 as a first-line treatment in newly-diagnosed, unmethylated GBM patients being conducted at Sun Yat-sen University Cancer Center in China.

"These interim data updates at the AACR Annual Meeting continue to demonstrate VAL-083's potential as a game-changing treatment option for GBM patients," commented Saïid Zarrabian, Kintara's Chief Executive Officer. "Furthermore, it's important to note that both trials have provided valuable insights as we prepared to initiate the VAL-083 arm of the Global Coalition for Adaptive Research GBM AGILE registrational study which commenced patient enrollment in February 2021."

Poster CT238: "Phase 2 study of dianhydrogalactitol (VAL-083) in patients with MGMT-unmethylated, bevacizumab-naïve glioblastoma in the adjuvant or recurrent setting"

In newly-diagnosed patients receiving VAL-083 as adjuvant therapy following treatment with radiation and temozolomide (TMZ), for the 33 efficacy evaluable patients (of a planned 36 patients) as of the data cut-off of March 12, 2021, median progression-free survival (PFS) is currently 10.0 months (95% confidence interval: CI 8.2-10.8). While not a head-to-head study, this PFS data compares favorably to historical TMZ control of 5.3 months* and 6.9 months**, respectively.

For patients in the fully enrolled recurrent group receiving second-line therapy with VAL-083 following first-line TMZ failure, 89 patients have been enrolled as of the data cut-off of March 12, 2021 with 35 patients (35 efficacy evaluable) initially receiving a dose of 40 mg/m²/day

and 54 (48 efficacy evaluable) initially receiving the treatment dose that is being carried forward in the GBM AGILE study of 30 mg/ m²/day on days 1, 2 and 3 of a 21-day cycle. Median overall survival (mOS) for the 83 efficacy evaluable patients who have completed at least once cycle of treatment was 7.5 months (CI 6.0-9.0 months). Additionally, for the 48 efficacy evaluable patients initially receiving a dose of 30 mg/ m²/day, mOS is currently 7.9 months (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 is the most common adverse event with VAL-083 in both the recurrent GBM and adjuvant treatment settings. In the 30 mg/m²/day starting dose cohort (the dose that is being carried forward in the GBM AGILE study) seven subjects have experienced a serious adverse event (SAE) possibly related to VAL-083 in the recurrent group and one patient has experienced a possibly drug-related SAE in the adjuvant group as of the relevant data cut-off dates.

Poster CT172: "Phase 2 clinical trial of dianhydrogalactitol (VAL-083) in patients with newly-diagnosed MGMT-unmethylated GBM"

In the open-label, Phase 2 study of VAL-083 as a first-line treatment in newly-diagnosed, unmethylated GBM patients, median PFS for the 29 patients, as of the March 11, 2021 cut-off date, is currently 9.3 months (CI 6.4-12.0 months). Additionally, for the 25 patients initially receiving the treatment dose that is being carried forward in the GBM AGILE study of 30 mg/m²/day on days 1, 2 and 3 of a 21-day cycle, median PFS was reported to be 8.7 months (CI 6.4-12.5 months). While not a head-to-head study, this PFS data compares favorably to historical TMZ control of 5.3 months* and 6.9 months**, respectively. Three subjects have experienced an SAE possibly related to VAL-083. Multiple treatment cycles of VAL-083 at the 30 mg/m²/day dose in combination with standard radiation treatment (2 Gy/day, 5 days/week) were shown to be generally safe and well-tolerated. This study has been fully enrolled, and all patients have completed treatment with VAL-083 and are currently in follow-up.

*Hegi et al *N Eng J Med* 352; 997-1003 (2005)

**Tanguturi et al. *NeuroOncol.* 19(7): 908-917 (2017)

*** 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 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 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](https://twitter.com/Kintara_Thera), [Facebook](https://www.facebook.com/Kintara_Thera) and [Linkedin](https://www.linkedin.com/company/kintara-therapeutics).

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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