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DelMar Pharmaceuticals [Nasdaq:DMPI] Enrolls Final Patient in Phase 2 Clinical Trial of VAL-083 For First-Line Treatment of Brain Tumors

Company Anticipates Earlier Than Expected Preliminary Data Readout in August 2020

SAN DIEGO, Feb. 19, 2020 /PRNewswire/ --DelMar Pharmaceuticals, Inc. (Nasdaq: DMPI) ("DelMar" or the "Company"), a biopharmaceutical company focused on the development of new solid tumor cancer therapies, announced it has enrolled and begun dosing the final patient in its ongoing Phase 2 clinical study investigating the first-line treatment of VAL-083 with radiation therapy in newly-diagnosed, MGMT-unmethylated glioblastoma multiforme (GBM). The trial, which is being conducted at the Sun Yat-sen University Cancer Center (SYSUCC) in Guangzhou, China, and in collaboration with Guangxi Wuzhou Pharmaceutical Company, is designed to enroll up to 30 patients to determine whether first-line therapy with VAL-083 treatment improves progression free survival (PFS). The current standard of care is first-line temozolomide (TMZ) with radiation.

"We are very pleased to have enrolled and started dosing our final patient in this important study. This earlier than predicted full enrollment is encouraging and will allow an earlier topline data readout," commented Professor Zhong-ping Chen, founder chairman of the Department of Neurosurgery/Neuro-oncology at Sun Yat-sen University Cancer Center, and who is also the study's principal investigator. "The enrollment of the final patient also provides us the opportunity to corroborate the preliminary data we've recently published, which supports the possibility that VAL-083 can provide a new and valuable treatment option in this difficult-to-treat indication."

The Phase 2 trial is a single-arm, open-label study testing VAL-083 in combination with standard radiotherapy in GBM patients who have an unmethylated promoter of the methylguanine DNA-methyltransferase (MGMT) gene. The clinical trial in newly-diagnosed GBM patients is designed to determine if first-line treatment with VAL-083 plus radiotherapy can provide improvements over the historical efficacy of standard of care TMZ plus radiotherapy. Efficacy will be measured based on tumor response to treatment, progression-free survival, progression-free survival at six months, and overall survival compared to historical results in the target population.

"Having completed enrollment of our first-line study ahead of schedule, we expect to complete analysis for the topline data in our most important Phase 2 trial for first-line GBM patients earlier than anticipated. We are optimistic that we will receive the initial data readout before the end of August 2020," commented Saiid Zarrabian, DelMar's Chief Executive Officer. "In the meantime, we continue to rapidly advance our other Phase 2 program in the adjuvant and recurrent settings for VAL-083 at MD Anderson Cancer Center and look forward to providing further updates on the progress of our ongoing open label GBM trials at upcoming scientific meetings."

DelMar has been monitoring the coronavirus situation in China. Based on discussions with our principal investigator at SYSUCC, we believe the coronavirus outbreak will not have a significant impact on our patient treatment timeline.

In addition to the Phase 2 clinical trial in first-line treatment, DelMar is conducting an additional two-arm Phase 2 clinical trial in GBM. The adjuvant arm, which initiated in late 2019 will enroll up to 24 newly-diagnosed patients who have undergone surgery and chemoradiation with TMZ but will now receive VAL-083 in place of standard of care TMZ for adjuvant therapy. The second arm treats patients with recurrent disease, administering VAL-083 in patients who have been heavily pre-treated with TMZ prior to disease recurrence. The recurrent arm will allow a total of 83 patients to be enrolled. Both arms are being conducted at the University of Texas MD Anderson Cancer Center.

About VAL-083

VAL-083 (dianhydrogalactitol) is a "first-in-class", bifunctional DNA-targeting agent that introduces inter-strand DNA cross-links at the N7-position of guanine leading to DNA double-strand breaks and cancer cell death. VAL-083 has demonstrated clinical activity against a range of cancers including GBM and ovarian cancer in historical clinical trials sponsored by the U.S. National Cancer Institute (NCI). DelMar has demonstrated that VAL-083's anti-tumor activity is unaffected by common mechanisms of chemoresistance, including MGMT, in cancer cell models and animal studies. Further details regarding these studies can be found at:

http://www.delmarpharma.com/scientific-publications.html.

About DelMar Pharmaceuticals, Inc.

Located in San Diego, California, DelMar is focused on the development and commercialization of new therapies for cancer patients who have limited or no treatment options. By focusing on understanding tumor biology and mechanisms of treatment resistance, the Company identifies biomarkers to personalize new therapies in indications where patients are failing, or are unable to tolerate, standard-of-care treatments.

The Company's current pipeline is based around VAL-083, 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 DelMar's internal research programs and these prior NCI-sponsored clinical studies, the Company is conducting clinical trials to support the development and commercialization of VAL-083 to solve significant unmet medical needs.

VAL-083 is being studied in two collaborator-supported, biomarker-driven Phase 2 clinical trials for MGMT-unmethylated GBM. Overcoming MGMT-mediated resistance represents a significant unmet medical need in the treatment of GBM. In addition, DelMar has announced the allowance of a separate IND for VAL-083 as a potential treatment for platinum-resistant ovarian cancer.

Further information on DelMar's clinical trials can be found on clinicaltrials.gov:
https://www.clinicaltrials.gov/ct2/results?cond=&term=val-083&cntry1=&state1=&recrs.
For additional information, please visit http://delmarpharma.com/; or contact DelMar Pharmaceuticals Investor Relations: ir@delmarpharma.com / (604) 629-5989.

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 reporting of the results. 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 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, 2019, the Company's Quarterly Reports on Form 10-Q, and the Company's Current Reports on Form 8-K.

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