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DelMar Pharmaceuticals Reports Updated Results on Twenty Patients from the Phase 2 Clinical Trial of VAL-083 as First-Line Treatment in Newly-Diagnosed MGMT-Unmethylated Glioblastoma MultiForme (GBM)

53% of assessed patients have achieved a complete response; 41% have achieved stable disease

VANCOUVER, British Columbia and MENLO PARK, Calif., Aug. 13, 2019 /PRNewswire/ - [DelMar Pharmaceuticals, Inc.](#) (NASDAQ: DMPI) ("DelMar" or the "Company"), a biopharmaceutical company focused on the development of novel cancer therapies, provided an update on the first 20 patients enrolled in its ongoing Phase 2 clinical study investigating the first-line treatment of VAL-083 in combination with radiation therapy in newly-diagnosed, MGMT-unmethylated GBM.

As of August 1, 2019, 17 of the first 20 enrolled patients have received at least their first assessment (two patients have not been enrolled long enough to receive their first assessment and one patient died before their first assessment). "Best Overall Response" for these patients per investigator assessment were:

- Nine have been assessed as having achieved a complete response (CR) (9/17, or 53%)
- Seven have been assessed with stable disease (SD), (7/17, or 41%)
- One has been assessed as disease progression (PD) (1/17, or 6%)

Importantly, 16 of the 20 patients enrolled (80%) were still alive as of the August 1, 2019 data cut-off date. The Company recently announced the enrollment of the 20th patient into this trial.

Dr. David Reardon, clinical director of the Center for Neuro-Oncology at the Dana-Farber Cancer Institute and Professor of Medicine at the Harvard Medical School, and Dr. John de Groot, Professor and Chairman ad interim in the Department of Neuro-Oncology at The University of Texas MD Anderson Cancer Center (MDACC), are considered key opinion leaders in the brain cancer field and currently serve as DelMar Scientific Advisory Board members. Dr. Reardon commented, "Both John and I agree that we desperately need something better to offer our patients and we feel that VAL-083 has some promise and potential."

Dr. Reardon added, "For a tumor such as GBM, which is intrinsically infiltrative and destructive in the brain, stabilization of disease is an important achievement."

Professor Zhong-ping Chen, Founder Chairman of the Department of Neurosurgery/Neuro-oncology at Sun Yat-sen University Cancer Center (SYSUCC), who is the study's principal investigator, stated, "We are pleased to be leading this Phase 2 trial for first-line GBM treatment with DelMar, and are encouraged by the enhanced levels of tumor shrinkage and the complete responses we are observing after treatment with VAL-083 in combination with radiation. These preliminary data appear to support the premise that VAL-083 has the potential to provide a valuable treatment option for these patients. We look forward to completing full enrollment in the study as soon as possible."

This Phase 2 trial which is being conducted at 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. Of the 20 patients enrolled, 17 (85%) have received their two-month (post-third cycle) MRI and investigator assessment, 13 (65%) have received their five-month MRI and investigator assessment, and seven (35%) have received their eight-month MRI and investigator assessment. Two patients (10%) have not been on the study long enough to reach their first assessment, and one patient (5%) died before their first assessment. Assessments are based on the trial investigator's clinical and radiologic assessment, according to the Response Assessment in NeuroOncology (RANO) criteria.

Saïd Zarrabian, DelMar's president and chief executive officer, noted, "We continue to be encouraged by these early results and look forward to the completion of enrollment for our two, late-stage, Phase 2 studies. These results support our optimism that VAL-083 may provide a better treatment option than currently available treatments."

This 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.

The Company also recently announced the initiation of an adjuvant arm to the MDACC study to provide early disease data on VAL-083. This arm 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. This arm is in addition to a trial arm treating 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, and both arms are being conducted at MDACC.

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.

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 & 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. 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, 2018, the Company's Quarterly Reports on Form 10-Q, and the Company's Current Reports on Form 8-K.

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