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DelMar Pharmaceuticals Receives Approval from MD Anderson Cancer Center's IRB for Protocol Expansion to Include Maintenance Stage MGMT-unmethylated GBM Patients in Ongoing Phase 2 Trial of VAL-083

VANCOUVER, British Columbia and MENLO PARK, Calif., April 3, 2019 /PRNewswire/ --[DelMar Pharmaceuticals, Inc.](#) (Nasdaq: DMPI) ("DelMar" or the "Company"), a biopharmaceutical company focused on the development and commercialization of new cancer therapies, today announced the University of Texas MD Anderson Cancer Center's (MDACC) Institutional Review Board (IRB) has approved a trial protocol amendment to expand DelMar's ongoing Phase 2 clinical trial of VAL-083 in patients with MGMT-unmethylated glioblastoma (GBM). The biomarker driven trial, which was originally designed as a single arm study evaluating VAL-083 in patients with MGMT-unmethylated bevacizumab (Avastin)-naïve recurrent GBM, has been expanded to include an additional maintenance-stage (adjuvant therapy) treatment group.

This protocol amendment, in addition to the Company's ongoing Phase 2 trial in newly diagnosed patients with MGMT-unmethylated GBM being conducted at Sun Yat-sen University Cancer Center (SYSUCC), expands DelMar's evaluation range of VAL-083 as a potential treatment for unmethylated GBM patients to include newly-diagnosed, maintenance-stage, and recurrent patients. Maintenance-stage GBM provides the greatest opportunity to control disease progression after radiation therapy, and represents the largest addressable GBM market opportunity for VAL-083 given patients are typically healthier and as such, are able to optimally benefit therapeutically from increased treatment cycles compared to the recurrent treatment setting. Maintenance GBM patients may be able to receive 12+ cycles of VAL-083 versus 5 or 6 cycles for recurrent GBM patients.

"VAL-083 offers a unique therapeutic approach that is independent of MGMT promoter status, has been shown to be safe, and may provide a valuable treatment option for the over 60% of patients with MGMT promoter unmethylated GBM who do not currently have strong chemotherapy options. As such, we are excited to expand the ongoing clinical trial at MD Anderson Cancer Center to include up to 24 maintenance (adjuvant) stage patients in the new treatment arm. This provides trial patients with VAL-083 much earlier than in the recurrent setting, and in lieu of adjuvant therapy with TMZ, which is acknowledged to be of limited value in this patient population," commented Principal Investigator Dr. Barbara O'Brian, Assistant Professor, Department of Neuro-Oncology, MD Anderson Cancer Center.

"The MGMT-unmethylated GBM patient population represents a significant unmet medical need and in fact, the 2017 NCCN guidelines highlight the inadequacy of currently approved therapies for these patients, who represent the majority of GBM cases. As the only company with late stage clinical assets focused on this underserved patient population, we are extremely pleased with the MDACC's IRB approval to expand the Phase 2 trial to include the MGMT-unmethylated patients in the maintenance-stage setting," commented Saiid Zarrabian, President and Chief Executive Officer of DelMar Pharmaceuticals. "Moving forward, we will continue to maintain our clinical development focus on this biomarker-enriched patient population while leveraging our fast track status with the FDA to optimize the path to a potential regulatory approval."

The additional maintenance-stage treatment group is expected to enroll up to 24 newly diagnosed GBM patients who have completed chemo-radiation treatment with temozolomide (TMZ) without the continued TMZ maintenance therapy as provided for on the label. The trial will determine if intervention prior to TMZ maintenance therapy offers clinical benefit and extends the time to recurrence as compared to TMZ maintenance. In addition, the protocol amendment provides for enrollment of up to 35 additional patients for the ongoing recurrent patient trial arm to enable the trial arm to maintain the originally planned statistical powering.

About VAL-083

VAL-083 (Dianhydrogalactitol) is a novel bi-functional DNA targeting agent that rapidly induces interstrand cross-

links at N7-guanine, leading to DNA double-strand breaks and ultimately cell death. VAL-083's unique cytotoxic mechanism circumvents MGMT mediated chemoresistance and differentiates it from other therapies used in the treatment of GBM, including TMZ. This makes VAL-083 an ideal candidate to explore treating patients who are unlikely to respond to TMZ due to MGMT expression in their GBM as per the 2017 National Comprehensive Cancer Network guidelines (NCCN).

VAL-083 has been granted orphan drug designations by the U.S. FDA Office of Orphan Products for the treatment of glioma, medulloblastoma and ovarian cancer, and in Europe for the treatment of malignant gliomas. VAL-083 has been granted fast-track status for the treatment of recurrent GBM by the US FDA.

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 National Cancer Institute (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): <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.

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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 Phase 2 clinical trial discussed above and the current results and outcomes of such trial. 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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