February 20, 2019

DelMar Pharmaceuticals Achieves Halfway Enrollment Point for Phase 2 Clinical Trial of VAL-083 in Newly Diagnosed MGMT-unmethylated GBM

- Complete Response Rate of 42% as Assessed by Principal Investigator Supports VAL-082's Activity in GBM -

VANCOUVER, British Columbia and MENLO PARK, Calif., Feb. 20, 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 that its Phase 2 study testing VAL-083 in patients with newly diagnosed glioblastoma multiforme (GBM) has achieved its halfway enrollment point. This trial, targeted to enroll up to thirty patients, 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. An estimated 60% of GBM patients possess an unmethylated MGMT gene, which confers a more limited response to current standard of care treatment as well as a lower survival probability. This clinical trial was initiated in February 2017 and is being conducted at the Sun Yat-sen University Cancer Center (SYSUCC) in Guangzhou, China in collaboration with Guangxi Wuzhou Pharmaceutical Company.

The Company is pleased to report that for the 15 patients enrolled to date, 11 have completed their prospectively planned Magnetic Resonance Imaging (MRI) scans and have had their initial assessment for tumor progression. Tumor progression is based on the trial investigator's clinical and radiologic assessment, according to the Response Assessment in NeuroOncology (RANO) criteria. Of these 11 patients, five were assessed by the Principal Investigator as having a "Complete Response", three of whom were based on significant tumor shrinkage, and two of whom were based on their tumors continuing to remain "below measurable level" from post-surgery baseline MRI to post-cycle 3 MRI. Additionally, six patients were assessed as having "Stable Disease." Of the remaining four patients, one died prior to their post-cycle 3 MRI and three have not been on study long enough to reach their planned post-cycle 3 MRI. As of the February 14, 2019 data cutoff, 12 of the 15 enrolled patients are still alive. Similar to prior experience, myelosuppression has been the most common adverse event observed. Two dose-limiting toxicities have been reported (thrombocytopenia) - one at the 40 mg/m^2/day dose and one at the 30 mg/m^2/day dose.

"GBM is a cancer with a very high unmet medical need, especially for patients with an MGMT-unmethylated biomarker who are provided with limited existing treatment options," stated Saiid Zarrabian, President and Chief Executive Officer of DelMar Pharmaceuticals.

"We are encouraged that we have completed the dose escalation stage of this study and that 30 mg/m^2/day of VAL-083 in combination with radiation therapy was generally safe and well-tolerated in this trial. And while these results are preliminary, we are also enthusiastic that five of the first twelve patients available for efficacy measurements have initially been assessed as having a Complete Response. With the clinical trial rapidly enrolling into its expansion phase, we look forward to providing a final data update once the study is completed."

The Company will be providing further details and an update on this trial at the annual meeting of the American Association for Cancer Research being held March 29 to April 3, 2019.

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, stated that "treating glioblastoma patients with an unmethylated MGMT promoter is particularly challenging. While the clinical trial is still early, and we are only at the halfway point in enrollment, we are highly encouraged at the enhanced levels of tumor shrinkage and the complete responses we are observing after treatment with VAL-083 in combination with radiation. This preliminary data appears to support the premise that VAL-083 has the potential to provide a valuable treatment option for these patients."

The clinical trial in newly diagnosed GBM is designed to enroll up to 30 patients to determine if first-line treatment with VAL-083 plus radiotherapy can provide improvements over the historical efficacy of standard of care temozolomide (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 clinical trial consists of two parts:

1. Part 1 is a dose-escalation and induction format to confirm the recommended dose of VAL-083 when administered concurrently with radiation therapy based on safety and tolerability. The patients received VAL-083 at 20 mg/m^2/day, 30 mg/m^2/day or 40 mg/m^2/day along with standard radiation treatment. The dose escalation phase of the study was concluded in October 2018.
2. Part 2 comprises an expansion phase whereby VAL-083 will be studied in up to 20 additional patients. Based on the best balance of efficacy and tolerability, the dose of VAL-083 chosen for the expansion phase of the study was 30 mg/m^2/day. This phase of the study is ongoing and is continuing to enroll patients.

This phase 2 clinical trial (ClinicalTrials.gov Identifier: NCT03050736) is expected to provide the scientific basis for larger studies to support submission of marketing applications. Ideally, data from these larger studies will result in approval of VAL-083 as first line therapy for all newly-diagnosed patients with an unmethylated MGMT gene promoter.

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.

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/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.

Connect with the Company on Twitter, LinkedIn, Facebook, and Google+.

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.

View original content to download multimedia:http://www.prnewswire.com/news-releases/delmar-pharmaceuticals-achieves-halfway-enrollment-point-for-phase-2-clinical-trial-of-val-083-in-newly-diagnosed-mgmt-unmethylated-gbm-300798495.html

SOURCE DelMar Pharmaceuticals, Inc.