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DelMar Pharmaceuticals Achieves Two-Thirds Enrollment for Phase 2 Clinical Trial of VAL-083 As First-Line Treatment in Newly-Diagnosed MGMT-Unmethylated Glioblastoma MultiForme (GBM)

Recent Milestone Demonstrates Continued Progress Across Three Concurrent Studies of VAL-083 in Different Phases of GBM Progression

VANCOUVER, British Columbia and MENLO PARK, Calif., July 31, 2019 /PRNewswire/ -- [DelMar Pharmaceuticals, Inc.](#) (NASDAQ: DMPI) ("DelMar" or the "Company"), a biopharmaceutical company focused on the development of novel cancer therapies, today announces it has achieved two-thirds enrollment in its ongoing Phase 2 clinical study investigating the first-line treatment of VAL-083 with radiation therapy in newly-diagnosed MGMT-unmethylated 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.

"While treating glioblastoma patients with an unmethylated MGMT promoter is particularly challenging, we have been encouraged by the enhanced levels of tumor shrinkage observed to date following treatment with VAL-083 in combination with radiation," 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. "Having reached this two-thirds enrollment point, we look forward to seeing further results corroborating the preliminary data we've received, which does appear to support the premise that VAL-083 may provide an additional and valuable treatment option for these difficult-to-treat patient conditions."

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 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.

"This first line study continues to enroll at a consistent pace, and we look forward to completing enrollment in this very important patient population. Once complete, we believe that the data from this study may provide additional support for the advancement of the adjuvant setting trial at MD Anderson Cancer Center, as well as to potentially support a future US study for utilization of VAL-083 as a first-line therapy for newly-diagnosed patients with an unmethylated MGMT gene promoter," commented Saiid Zarrabian, DelMar's Chief Executive Officer. "In the meantime, we are very proud to be advancing all three of our Phase 2 programs for VAL-083, including the two-arm trial being conducted at MD Anderson Cancer Center in Texas for patients with recurrent GBM and those who have undergone surgery and chemoradiation with TMZ but will now receive VAL-083 in place of standard of care TMZ for adjuvant therapy. We look forward to continuing to provide updates on the progress of all three patient populations."

The company recently announced the initiation of an adjuvant arm to the MD Anderson 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 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.

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):
<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.

CONTACTS:

Investors:

John Marco
Managing Director
CORE IR
516-222-2560
johnm@coreir.com

Media:

Jules Abraham
Director of Public Relations
CORE IR
917-885-7378
julesa@coreir.com



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