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DelMar Pharmaceuticals Announces Dosing of the First Patient in Phase Two Clinical Trial of VAL-083 for MGMT-unmethylated Recurrent Glioblastoma Multiforme (GBM)

Study is currently enrolling MGMT-unmethylated Avastin (bevacizumab)-naïve recurrent GBM patients at the University of Texas MD Anderson Cancer Center

VANCOUVER, British Columbia and MENLO PARK, Calif., Feb. 13, 2017 /PRNewswire/ -- DelMar Pharmaceuticals, Inc. (NASDAQ: DMPI) ("DelMar" and the "Company"), a biopharmaceutical company focused on the development and commercialization of new cancer therapies, announced today that patient dosing has commenced in a Phase 2 clinical study of its investigational drug VAL-083 *(dianhydrogalactitol)* for MGMT-unmethylated Avastin® (bevacizumab)-naïve recurrent glioblastoma.

The first patient was dosed by DelMar's collaborators at the University of Texas MD Anderson Cancer Center in Houston Texas.

"The dosing of the first subject in this VAL-083 trial marks an important milestone in the advancement of our clinical development program targeting MGMT-unmethylated GBM," said Jeffrey Bacha, chairman & CEO of DelMar Pharmaceuticals.

"The majority of newly diagnosed GBM patients' tumors are characterized as MGMT-unmethylated, which is directly correlated with resistance to current standard front-line chemoradiation with temozolomide," added Mr. Bacha. "Our research demonstrates that VAL-083 is active independent of MGMT expression. These data, combined with data from prior clinical trials sponsored by the US National Cancer Institutes that establish VAL-083's activity against GBM, are the foundation of our belief that VAL-083 may provide a new therapeutic option for GBM patients whose tumors exhibit features making them resistant or unlikely to respond to currently available therapy."

The Phase 2 trial will test safety, tolerability and clinical efficacy of VAL-083 in 48 adult subjects with MGMT-unmethylated GBM whose tumors have recurred following surgery and standard chemo-radiation with temozolomide. Patients will receive 40 mg/m2 VAL-083 (IV) on days 1, 2, and 3 of a 21-day treatment-cycle, for up to twelve 21-day treatment cycles to determine if treatment with VAL-083 improves overall survival compared to historical controls. Further information regarding the clinical trial can be found on DelMar's website

and at clinicaltrials.gov *(clinicaltrials.gov identifier: NCT02717962).*

Approximately two-thirds of newly diagnosed GBM patients have tumors with an unmethylated MGMT promoter, which is correlated with high expression of the DNA repair enzyme, MGMT. Published studies have documented that expression of MGMT is an important factor in predicting the outcome of GBM patients treated with alkylating agents such as temozolomide (TMZ), carmustine (BCNU), and lomustine (CCNU).

Patients whose tumors exhibit a high expression of MGMT have a poor prognosis and significantly shorter progression free survival (PFS) and overall survival (OS) in comparison to patients with a methylated MGMT promoter and low MGMT expression. In a 2011 study of more than 800 newly diagnosed GBM patients, those with tumors carrying the unmethylated MGMT promoter had a median overall survival of 14 months versus 21 months for those with a methylated MGMT promoter. The difference in progression-free survival – the period after treatment during which the cancer does not worsen – was 5.7 and 8.7 months, respectively.

About VAL-083

VAL-083 is a "first-in-class," small-molecule chemotherapeutic that demonstrated clinical activity against a range of cancers including GBM in historical clinical trials sponsored by the U.S. National Cancer Institutes. DelMar has demonstrated that VAL-083's anti-tumor activity against GBM is unaffected by the expression of MGMT *in vitro.* Further details can be found at http://www.delmarpharma.com/scientific-publications.html.

VAL-083 has received an orphan drug designation in Europe for the treatment of malignant gliomas and the U.S. FDA Office of Orphan Products has granted an orphan designation to VAL-083 for the treatment of glioma, medulloblastoma and ovarian cancer.

DelMar has also announced plans to advance VAL-083 into a pivotal randomized multi-center Phase 3 clinical trial for the treatment of bevacizumab-failed GBM and into a separate international Phase 2 trial for newly diagnosed MGMT-unmethylated GBM.

DelMar believes that data from its clinical trials, if successful, will form the basis of a new treatment paradigm for the vast majority of GBM patients whose tumors exhibit features that make them unlikely to respond to currently available therapies.

About Glioblastoma Multiforme (GBM)

GBM is the most common and the most lethal form of brain cancer. Approximately 15,000 new cases of GBM are expected to be diagnosed in the United States during 2017. GBM progresses quickly and patients deteriorate rapidly. Common symptoms include headaches, seizures, nausea, weakness, paralysis and personality or cognitive changes such as loss of speech or difficulty in thinking clearly. The majority of GBM patients do not survive for more than two years following diagnosis, and the median survival in newly diagnosed patients with best available treatments is less than 15 months.

About DelMar Pharmaceuticals, Inc.

DelMar Pharmaceuticals, Inc. was founded to develop and commercialize new cancer therapies in indications where patients are failing or have become intolerable to modern

targeted or biologic treatments. DelMar's VAL-083 is currently undergoing clinical trials in the U.S. as a potential treatment for refractory glioblastoma multiforme. VAL-083 has been extensively studied by the U.S. National Cancer Institutes, and is currently approved for the treatment of chronic myelogenous leukemia and lung cancer in China. Published pre-clinical and clinical data suggest that VAL-083 may be active against a range of tumor types via a novel mechanism of action that could provide improved treatment options for patients.

For further 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. 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 our filings with the SEC, including, our current reports on Form 8-K.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/delmar-pharmaceuticals-announces-dosing-of-the-first-patient-in-phase-two-clinical-trial-of-val-083-for-mgmt-unmethylated-recurrent-glioblastoma-multiforme-gbm-300406006.html

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