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DelMar Pharmaceuticals Initiates Phase 2 Clinical Trial in Newly Diagnosed MGMT-unmethylated Glioblastoma Multiforme

VANCOUVER, British Columbia and MENLO PARK, Calif., Sept. 11, 2017 /PRNewswire/ - DelMar Pharmaceuticals (Nasdaq: DMPI) ("DelMar" and "the Company"), a biopharmaceutical company focused on the development of new cancer therapies, today announced the initiation of a Phase 2 clinical trial for its lead agent VAL-083 in newly diagnosed MGMT-unmethylated glioblastoma multiforme (GBM). The biomarker-driven clinical trial will explore safety and efficacy of chemoradiation with VAL-083 as an alternative to standard-of-care temozolomide in patients with MGMT-unmethylated GBM.

"This small trial has the ability to pave the way for a significant treatment paradigm change for patients with newly diagnosed GBM. Positive data from this study will serve as a lead-in to a randomized global trial and set the stage for VAL-083 to potentially become the standard of care for approximately two-thirds of newly diagnosed GBM patients," commented Jeffrey Bacha, Chief Executive Officer of DelMar Pharmaceuticals.

The trial, which is being funded under the terms of DelMar's collaboration with Guangxi Wuzhou Pharmaceutical Group Co. Ltd. (Guangxi Wuzhou Pharma), is being conducted at Sun Yat-sen University Cancer Center (SYUCC) in Guangzhou, China under the direction of Prof. Zhong-ping Chen, M.D., Ph.D. Prof. Chen is the Chair of the Department of NeuroSurgery/Neuro-Oncology at SYUCC and a member of the editorial board of the Journal of NeuroOncology.

The study will enroll 20-30 newly diagnosed GBM patients whose tumors exhibit high-expression of the DNA-repair enzyme O⁶-methylguanine methyltransferase (MGMT) and will be treated with VAL-083 in combination with radiotherapy to examine the safety and efficacy of VAL-083 in this population. MGMT methylation status will be used as a biomarker for patient selection and only patients whose tumors are MGMT-unmethylated will be enrolled.

GBM patients with MGMT-unmethylated tumors exhibit a high expression of the MGMT enzyme. MGMT expression is correlated with resistance to temozolomide, the current front-line chemotherapy used in the treatment of GBM. MGMT-unmethylated patients have particularly poor patient outcomes and significantly reduced survival compared to MGMT-methylated patients. VAL-083 has demonstrated anti-cancer activity independent of MGMT expression against multiple GBM cell lines *in vitro*.

The primary efficacy endpoint of this trial is progression free survival (PFS). Based on enrollment projections, it is expected that safety/tolerability and primary efficacy (PFS) data from this trial will become available within 9 months and 15 months, respectively from start of enrollment. Results will be used to guide the design of global randomized studies, which if

successful, will position VAL-083 as a potential replacement for the current standard-of-care (chemoradiation with temozolomide) in newly diagnosed GBM patients, particularly for the approximately 2/3 of patients whose tumors feature MGMT-unmethylated GBM. Further details of the trial can be found at clinicaltrials.gov (Identifier Number: NCT03050736)

About VAL-083

VAL-083 (dianhydrogalactitol) is a "first-in-class", DNA-targeting agent that introduces interstrand 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 in historical clinical trials sponsored by the U.S. National Cancer Institutes (NCI).

VAL-083 has been granted an orphan drug designation 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.

DelMar has demonstrated that VAL-083's anti-tumor activity against GBM is unaffected by the expression of MGMT in vitro. Further details regarding these studies can be found at <http://www.delmarpharma.com/scientific-publications.html>.

The Company's recent outcomes in Phase 1-2 clinical trials suggested that VAL-083 may offer a clinically meaningful survival benefit for patients with recurrent GBM following treatment with both TMZ and bevacizumab. A well-tolerated dosing regimen of 40mg/m²/day on days 1, 2, and 3 of a 21-day cycle was selected for study in subsequent GBM clinical trials.

Overall VAL-083's clinical activity as a potential treatment for GBM has been established by DelMar's recent clinical trials in refractory GBM and historical trials conducted by the NCI. In prior NCI trials, VAL-083 combined with radiotherapy in newly diagnosed GBM (all MGMT status) demonstrated superior benefit versus radiotherapy alone (8.3 months) in comparison to similar studies involving temozolomide or nitrosoureas (1.2 – 2.5 months).

Based on these results, DelMar has embarked on human clinical trials for VAL-083 across multiple lines of GBM therapy. These trials include, i) an ongoing single-arm, biomarker driven, Phase 2 study to determine if VAL-083 treatment of MGMT-unmethylated adult GBM patients at first recurrence/progression, prior to bevacizumab, improves overall survival, compared to historical control with lomustine (clinicaltrials.gov identifier: NCT02717962); ii) a pivotal, randomized Phase 3 study in temozolomide-Avastin Recurrent GBM ("STAR-3") to evaluate overall survival versus salvage chemotherapy (clinicaltrials.gov identifier: NCT03149575); iii) a single arm, biomarker driven, Phase 2 study to confirm the tolerability and efficacy of VAL-083 in combination with radiotherapy in newly diagnosed MGMT-unmethylated GBM patients whose tumors are known to express high MGMT levels (clinicaltrials.gov identifier: NCT03050736). The results of these studies may support a new treatment paradigm in chemotherapeutic regimens for the treatment of GBM.

About Glioblastoma Multiforme (GBM)

Glioblastoma Multiforme (GBM) is the most common and aggressive primary brain cancer. Approximately 18,000 patients are diagnosed with GBM in the United States and 25,000 in

Europe each year. Current standard of care includes surgery, radiation and treatment with temozolomide (TMZ), however nearly all tumors recur and the prognosis for recurrent GBM is dismal. Approximately two-thirds of newly diagnosed GBM patients have tumors characterized by an unmethylated promoter for O⁶-methylguanine methyltransferase (MGMT); a validated biomarker for TMZ-resistance. Second-line treatment with anti-angiogenic agent bevacizumab has not improved overall survival (OS) and 5-year survival is less than 3%.

About DelMar Pharmaceuticals, Inc.

DelMar Pharmaceuticals, Inc. is developing cancer therapies in indications where patients are failing, or have become intolerable to, modern targeted or biologic treatments. The Company's 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 GBM, ovarian and other solid tumors (e.g. NSCLC, bladder cancer, head & neck) in U.S. clinical trials sponsored by the NCI. VAL-083 has been granted an orphan drug designation 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 glioma. In 2017, the Company plans to file an IND for VAL-083 in ovarian cancer, enter into a pivotal randomized multi-center Phase 3 clinical trial for the treatment of bevacizumab-failed GBM, continue to enroll a Phase 2 trial (with MD Anderson Cancer Center) in first recurrence GBM patients prior to bevacizumab therapy, and commence a separate international Phase 2 trial for newly diagnosed MGMT-unmethylated GBM.

For further information, please visit <http://delmarpharma.com/>; or contact DelMar Pharmaceuticals Investor Relations: ir@delmarpharma.com / (604) 629-5989.

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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.



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