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DelMar Pharmaceuticals Announces Completion of First Site Initiation Visit for STAR-3 Pivotal Phase 3 Clinical Trial of VAL-083 in Refractory GBM

VANCOUVER, British Columbia and MENLO PARK, Calif., July 18, 2017 /PRNewswire/ -- DelMar Pharmaceuticals (Nasdaq: DMPI) ("DelMar" and "the Company"), a biopharmaceutical company focused on the development of new cancer therapies, today announced the completion of the first site initiation visit at the Dent Neurological Institute ("Dent") for its pivotal Phase 3 **S**tudy in **T**emozolomide-**A**vastin (bevacizumab) **R**ecurrent GBM ("STAR-3"). Site initiation visits are generally the final step before patient enrollment.

The STAR-3 GBM trial is an adaptive design, randomized, controlled pivotal Phase 3 clinical trial to assess the efficacy and safety of VAL-083 versus salvage therapy in patients with late-stage glioblastoma multiforme (GBM) whose disease has progressed following prior treatment with temozolomide and bevacizumab, for whom there is currently no standard-of-care therapy.

The Dent Neurological Institute is the largest private neurology center in North America seeing more than 250,000 patients annually. Dr. Laszlo Mechtler will serve as principal investigator for the STAR-3 trial at Dent. Dr. Mechtler is Medical Director of Dent Neurologic Institute as well as the Chief of Neuro-Oncology at Roswell Park Cancer Institute in Buffalo, NY. He has contributed to numerous publications and is currently the Principle Investigator of multiple clinical research protocols related to Neuro-Oncology. DelMar anticipates the initiation of additional centers and commencement of treatment under the STAR-3 protocol in the coming weeks.

A total of up to 180 eligible patients will be randomized at approximately 25 centers in the United States to receive either the investigational drug (VAL-083) or "investigator's choice salvage therapy" in a 2:1 fashion. Up to 120 eligible patients will be randomized to receive intravenous VAL-083 at 40 mg/m2 on days 1, 2, and 3 of a 21-day treatment cycle, for up to 12 21-day treatment cycles or until they fulfill one of the criteria for study discontinuation. Up to 60 patients will be randomized to "investigator's choice" control, limited to temozolomide, lomustine, or carboplatin, until they fulfill one of the criteria for study discontinuation.

The primary endpoint of the trial is overall survival of VAL-083 vs. the control arm. The statistical design between the two arms of the study is 90% power, and is proposed to include an interim analysis at 50% events for futility with O'Brien-Fleming superiority boundary and non-binding, gamma (-5) futility boundary. A detailed description of the STAR-3 trial can be found at clinicaltrials.gov, Identifier Number: NCT03149575.

"The activation of the STAR-3 trial and initiation of recruitment in collaboration with Dr. Mechtler and his team at Dent is a momentous occasion for our Company, and for the patients and their families who we hope will benefit from VAL-083," commented Jeffrey Bacha, chief executive officer of DelMar Pharmaceuticals. "In particular, GBM is a type of cancer that has been devoid of new drug approvals improving overall survival for decades, which is why we believe that VAL-083 represents tremendous value in the oncology treatment market. We are pleased to be launching this pivotal study to validate VAL-083's potential by meeting the objectives in the STAR-3 trial."

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.

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/m^2/day on days 1, 2, and 3 of a 21-day cycle was selected for study in subsequent GBM clinical trials.

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, controlled 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 (GBM) is the most common and aggressive primary brain cancer. 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. Most GBM tumors have unmethylated promoter status for O6-methylguanine-DNA-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 National Cancer Institute (NCI). 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 treat patients in 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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