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DelMar Pharmaceuticals Announces Fast Track Designation for VAL-083 in Recurrent Glioblastoma

- Supports Lead Program, VAL-083, in Ongoing Clinical Trials -

VANCOUVER, British Columbia and MENLO PARK, Calif., Dec. 26, 2017 /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 the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the company's lead product candidate, VAL-083, in recurrent glioblastoma (rGBM).

"The Fast Track designation marks an important milestone in the development of VAL-083 as a potential new therapy for cancer patients with limited or no treatment options," said Saiid Zarrabian, interim chief executive officer at DelMar. "We appreciate the FDA's recognition that the VAL-083 program addresses a significant unmet need in rGBM as we continue to evaluate this agent in patients with multiple tumor types."

This Fast Track status applies to two ongoing clinical trials sponsored by DelMar Pharmaceuticals to evaluate VAL-083 as a potential treatment for rGBM. These trials include:

- A Phase 2 study in bevacizumab-naïve MGMT-unmethylated GBM patients conducted in collaboration with The University of Texas MD Anderson Cancer Center; and
- A Phase 3 study of patients whose disease has progressed following prior treatment with temozolomide and bevacizumab (the STAR-3 trial).

Fast track designation is designed to expedite the review of drugs that show promise in treating life-threatening diseases and address unmet medical needs, with the goal of getting new treatments to patients earlier. Fast Track designation provides sponsors with an opportunity for increased frequency of communication with FDA to ensure an optimal development plan and to collect appropriate data needed to support drug approval.

Additional benefits of the Fast Track designation may include an Accelerated Approval, a Priority Review, and a Rolling Review. Accelerated Approval is granted to drugs that demonstrate an effect on a surrogate, or intermediate endpoint reasonably likely to predict clinical benefit. Priority Review shortens the FDA review process for a new drug from ten months to six months, and is appropriate for drugs that demonstrate significant improvements in both safety and effectiveness of an existing therapy. Rolling Review provides a drug company the opportunity to submit completed sections of its New Drug Application (NDA) for review by the FDA. Typically, NDA reviews do not commence until the

drug company has submitted the entire application to the FDA. Through the Fast Track designation, the FDA attempts to ensure that questions raised during the drug development process are resolved quickly, often leading to earlier approval and increased access for patients.

Outside of rGBM, DelMar has initiated a Phase 2 clinical trial of VAL-083 in newly-diagnosed MGMT-unmethylated GBM. DelMar also recently received notice of allowance from the FDA of an IND for a Phase 1/2 trial of VAL-083 in patients with recurrent platinum-resistant ovarian cancer.

"Our ongoing VAL-083 clinical development program is supported by extensive preclinical research into the agent's unique mechanism of action, as well as promising data from prior clinical trials sponsored by DelMar and the National Cancer Institute," added Mr. Zarrabian. "We are enthusiastic about the potential of VAL-083 to offer a meaningful clinical benefit to patients with rGBM and for the opportunity to expedite the regulatory process through the FDA's Fast Track program."

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 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 *in vitro.* Further details regarding these studies can be found at http://www.delmarpharma.com/scientific-publications.html.

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.

About DelMar Pharmaceuticals, Inc.

DelMar Pharmaceuticals is focused on the development and commercialization of new therapies for cancer patients who have limited or no treatment options. By developing an understanding of tumor biology and mechanisms of treatment resistance, the Company identifies biomarkers to personalize new therapies in indications where patients are failing, or have become intolerable to modern targeted or biologic treatments.

The Company's current pipeline centers 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 across multiple oncology indications to solve significant unmet medical needs.

DelMar is currently studying VAL-083 in a Phase 3 clinical trial for GBM patients whose tumor has recurred following treatment with temozolomide and bevacizumab. VAL-083 is

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

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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.

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