DelMar Pharmaceuticals Receives IND Allowance from FDA to Initiate Clinical Trials of VAL-083 for the Treatment of Ovarian Cancer

VANCOUVER, British Columbia, and MENLO PARK, Calif., Sept. 18, 2017 /PRNewswire/ -- DelMar Pharmaceuticals, Inc. (Nasdaq: DMPI) ("DelMar" and "the Company"), a biopharmaceutical company focused on the development of new cancer therapies, today announced that the U.S. Food and Drug Administration ("FDA") has allowed an additional Investigational New Drug Application ("IND") to study its lead drug candidate VAL-083 as a potential treatment for ovarian cancer.

"The opening of this new IND to study VAL-083 in ovarian cancer marks a major milestone for our Company as we continue to investigate this agent as an important potential therapy for the treatment of multiple cancers," said Jeffrey Bacha, DelMar's president and chief executive officer.

VAL-083 is a first-in-class, DNA targeting agent that demonstrated clinical activity against a range of tumor-types in prior clinical trials sponsored by the U. S. National Cancer Institute ("NCI"). Published results from NCI studies include recommendations for further study of VAL-083 in advanced clinical trials for ovarian cancer and other gynecologic malignancies.

DelMar's clinical trial will be a multi-center, Phase 1/2 Study of VAL-083 in patients with Recurrent Platinum Resistant Ovarian Cancer ("VAL-083 REPROVe Trial"). DelMar's research demonstrates that VAL-083's unique mechanism of action has the potential to overcome chemo-resistance to platinum-based chemotherapy in ovarian, lung and other solid tumors.

Ovarian cancer remains the leading cause of death among women with gynecological cancers and the fifth most frequent cause of cancer deaths in women overall. The American Cancer Society estimates that in 2017, approximately 22,440 women in the US will be diagnosed with ovarian cancer and approximately 14,080 will die from their disease. The majority of these deaths were patients whose tumors had become resistant to platinum-based chemotherapy regimens. Currently, there are no high-efficacy therapeutic options for platinum-resistant ovarian cancer, leaving these cancer patients with very poor prognosis. According to published literature, the overall response rate ("ORR") to second line therapy is in the 10-15% range and overall survival is approximately 12-months.
"The development of new treatments to overcome platinum resistance represents the largest unmet medical need in the treatment of ovarian cancer," stated Dr. Bradley J. Monk, MD, principal investigator of the VAL-083 REPROVe Trial and director of the Division of Gynecologic Oncology Research at Arizona Oncology. "Based on DelMar's recent presentation of pre-clinical data demonstrating activity of VAL-083 against platinum-resistant ovarian cancer, we are enthusiastic about exploring the drug's potential in this important clinical setting."

About the VAL-083 REPROVe Trial

The VAL-083 REPROVe Trial is an open label, multi-center, Phase 1/2 clinical trial to evaluate the safety and efficacy of VAL-083 in patients with recurrent adenocarcinoma of the ovary, who have been previously treated with a minimum of two courses of platinum-based chemotherapy, and whose cancer has recurred within six months of the most recent platinum-based chemotherapy. Patients enrolled in the trial will receive VAL-083 intravenously once per week for 16 weeks or until disease progression.

VAL-083 activity against platinum-resistant ovarian cancer will be measured based on ORR using the Response Evaluation Criteria in Solid Tumors ("RECIST") version 1.1 criteria as well as response duration, progression free survival, and a measurement of CA-125 biomarker levels in the blood. The study's primary endpoint is to demonstrate an ORR benefit compared to historical control of 12-15%.

Twenty-four patients will be enrolled under the first phase of the VAL-083 REPROVe Trial with top line results expected within 18-24 months from trial initiation of patient treatment. DelMar plans to request a meeting with the FDA following the completion of Phase 1. If successful, DelMar expects that data from Phase 1 will lead to a Phase 2 expansion study. If Phase 2 is successful, and subject to FDA feedback, DelMar may be positioned to file an application for accelerated approval or, alternatively, to advance VAL-083 to a pivotal Phase 3 trial.

"Our planned work in ovarian cancer will be complementary to our ongoing Phase 2 and 3 clinical trials with VAL-083 as a potential treatment for refractory and MGMT-unmethylated glioblastoma multiforme ("GBM"). Based on our research, we believe that the REPROVe Trial has the potential to provide significantly improved outcomes for patients suffering from platinum-resistant ovarian cancer," added Mr. Bacha. Subject to availability of funding, DelMar anticipates opening the VAL-083 REPROVe Trial for patient enrollment in early 2018.

Further details on the VAL-083 REPROVe Trial and other VAL-083 clinical trials can be found at [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)

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. VAL-083 is currently being studied in multiple clinical trials as a potential new treatment for GBM, the most common and aggressive form of brain cancer.

DelMar has demonstrated that VAL-083’s mechanism of action is distinct from multiple chemotherapies widely used in the treatment of cancer and that this unique mechanism may offer opportunities to overcome treatment resistance thereby offering new treatment options to cancer patients. Further details regarding these studies can be found at http://www.delmarpharma.com/scientific-publications.html.

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 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 have become intolerable to modern targeted or biologic 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 across multiple oncology indications to solve significant unmet medical needs.

The STAR-3 trial is a multi-center, pivotal, randomized Phase 3 clinical study in bevacizumab (Avastin®) recurrent GBM. Outcomes in DelMar’s recent Phase 1-2 clinical trials suggest that VAL-083 may offer a clinically meaningful survival benefit for this patient population.

VAL-083 is also being studied in two collaborator-supported, biomarker driven, Phase 2 clinical trials for MGMT-unmethylated GBM as a potential alternative for the majority of GBM patients whose tumors exhibit high expression of MGMT, a biomarker correlated with resistance to the current standard-of-care chemotherapy. Overcoming MGMT-mediated resistance represents a significant unmet medical need in the treatment of GBM.

The VAL-083 REPROVe trial will explore VAL-083 in platinum-resistant ovarian cancer. Resistance to platinum-based chemotherapy represents a significant unmet medical need in the treatment of 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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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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