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DelMar's VAL-083 Demonstrates Promise in the Treatment of Non-Small Cell Lung Cancer and Ovarian Cancer

MD Anderson Researchers Presented New Pre-clinical Data Today at the American Association of Cancer Research (AACR) Annual Meeting

VANCOUVER, British Columbia and MENLO PARK, Calif., April 18, 2016 /PRNewswire/ -- [DelMar Pharmaceuticals, Inc.](#) (OTCQX: DMPI) ("DelMar" and the "Company"), a biopharmaceutical company focused on the development and commercialization of new cancer therapies, today announced that the Company's collaborators from the University of Texas MD Anderson Cancer Center (MD Anderson) presented new pre-clinical data supporting the promising potential of its lead anti-cancer product candidate, [VAL-083](#) (dianhydrogalactitol), in the treatment of non-small cell lung cancer (NSCLC) and ovarian cancer.



Abstract (#2157): "[Enhanced in vitro activity of dianhydrogalactitol \(VAL-083\) in combination with platinum drugs: Impact of p53 and platinum-resistance](#)," was presented at AACR during the "New Drugs, Therapeutic Targets, and Treatment Approaches" session.

In summary, MD Anderson researchers presented new in vitro data from their studies with VAL-083 indicating that:

- VAL-083 induces apoptosis independent of p53 status, and appears to have a distinct mode of action from platinum-based chemotherapies widely used in the treatment of NSCLC and ovarian cancer;
- VAL-083 demonstrated ability to circumvent cisplatin-resistance in all ovarian cell lines tested;
- VAL-083 was active against NSCLC tumors harboring T790M, p53 and/or KRAS mutations, known to confer resistance to currently available therapies; and
- VAL-083 demonstrated super-additivity or synergy in combination with platinum-based chemotherapy.

"These results support VAL-083 as a viable treatment option for refractory NSCLC and

ovarian cancer patients failing platinum-based therapy as well as the potential benefit of a VAL-083-platinum combination," said Jeffrey Bacha, DelMar's chairman & CEO.

Dr. Dennis Brown, DelMar's Chief Scientific Officer, added, "The activity of VAL-083 observed in tumors harboring mutations known to be correlated with resistant phenotypes and poor treatment outcomes provides clarity and direction as we advance toward planned clinical trials in NSCLC. We can use these biomarkers for patient selection in a personalized-medicine approach to establish clinical proof-of-concept in specific tumor sub-types representing significant unmet needs within the cancer treatment market."

DelMar previously announced plans to initiate clinical trials with VAL-083 in the treatment of NSCLC in cooperation with Guangxi Wuzhou Pharmaceutical (Group) Co., Ltd., who is to provide funding for the trial in accordance with the terms of a collaboration agreement.

About VAL-083

VAL-083 is a "first-in-class," small-molecule chemotherapeutic. In more than 40 Phase I and II clinical studies sponsored by the U.S. National Cancer Institute, VAL-083 demonstrated clinical activity against a range of cancers including lung, brain, cervical, ovarian tumors and leukemia both as a single-agent and in combination with other treatments. VAL-083 is approved in China for the treatment of chronic myelogenous leukemia (CML) and lung cancer, and has received orphan drug designation in Europe and the U.S. for the treatment of malignant gliomas. DelMar recently announced that the FDA's Office of Orphan Products had also granted an orphan designation to VAL-083 for the treatment of medulloblastoma.

DelMar has demonstrated that VAL-083's anti-tumor activity is unaffected by the expression of MGMT, a DNA repair enzyme that is implicated in chemotherapy resistance and poor outcomes in GBM patients following standard front-line treatment with Temodar® (temozolomide).

DelMar has been conducting a Phase I/II clinical trial in GBM patients whose tumors have progressed following standard treatment with temozolomide, radiotherapy, bevacizumab and a range of salvage therapies.

Data from the Phase I dose-escalation of the study suggest that VAL-083 is well tolerated using a regimen of 40mg/m² daily x 3 every 21 days. Dose limiting toxicity (DLT) defined by thrombocytopenia (low platelet counts) was observed at doses above 40 mg/m². Generally, DLT-related symptoms resolved rapidly and spontaneously without concomitant treatment.

Sub-group analysis of Phase I data suggests a dose-dependent and clinically meaningful survival benefit following treatment with VAL-083. Patients in a low dose (≤ 5 mg/m²) sub-group had a median survival of approximately five (5) months versus median survival of approximately nine (9) months for patients in the therapeutic dose (30mg/m² & 40mg/m²) sub-group following initiation of VAL-083 treatment. DelMar also reported increased survival at 6, 9 and 12 months following initiation of treatment with VAL-083 in the therapeutic dose sub-group compared to the low dose sub-group.

Based on these data, DelMar initiated a Phase II expansion cohort utilizing the 40mg/m² dosing regimen in June 2015 at five clinical centers in the United States: Mayo Clinic (Rochester, MN); UCSF (San Francisco, CA) and three centers associated with the Sarah Cannon Cancer Research Institute (Nashville, TN, Sarasota, FL and Denver, CO). DelMar

announced the completion of enrollment in a Phase II expansion cohort in September, 2015.

Updated interim data from this ongoing study will be presented on Tuesday April 19, 2016 at the AACR Annual Meeting in the Phase II/III Clinical Trials in Progress" session (Abstract #CT074).

Further details can be found at <http://www.delmarpharma.com/scientific-publications.html>.

About NSCLC

Lung cancer is a leading cause of cancer-related mortality around the world and effective treatment for lung cancer remains a significant global unmet need despite advances in therapy. In general, prognosis for lung cancer patients remains poor, with 5-year relative survival less than 14% among males and less than 18% among females in most countries. Globally, the market for lung cancer treatment may exceed \$7 billion by 2019 according to a report published by Transparency Market research.

Non-small cell lung cancer ("NSCLC") is the most common type of lung cancer. There are three common forms of NSCLC: adenocarcinomas are often found in an outer area of the lung; squamous cell carcinomas are usually found in the center of the lung next to an air tube (bronchus); and large cell carcinomas, which can occur in any part of the lung and tend to grow and spread faster than adenocarcinoma. NSCLC accounts for 85% of all lung cancer cases in the United States and approximately 90% of lung cancer cases diagnosed in China.

The current standard of care for newly diagnosed NSCLC is platinum-based combination therapy or tyrosine kinase inhibitor (TKI) therapy for patients whose cancer exhibits over expression of epidermal growth factor receptor ("EGFR") mutations. Patients exhibiting an over expression of EGFR mutations have shown an initial response rate to TKIs which exceeds the response rate for conventional chemotherapy. However, resistance to TKI therapy has emerged as an important unmet medical need commonly linked to the emergence of specific mutations such as T790M.

About Ovarian Cancer

The American Cancer Society estimates for 2015 about 21,290 women will receive a new diagnosis of ovarian cancer and approximately 14,180 women will die from ovarian cancer in the United States. Ovarian cancer ranks fifth in cancer deaths among women, accounting for more deaths than any other cancer of the female reproductive system. A woman's risk of getting ovarian cancer during her lifetime is about 1 in 75. Her lifetime chance of dying from ovarian cancer is about 1 in 100. Although initially responsive to standard-of-care chemotherapy based on platinum-taxane combinations, most tumors recur and median survival for recurrent ovarian cancer is 12 to 24 months. According to The Cancer Genome Atlas, there is a major clinical need for treatment with alternatives that can circumvent resistance to currently available chemotherapies.

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. The Company's lead drug in development, 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 Institute, 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 www.delmarpharma.com; or contact DelMar Pharmaceuticals Investor Relations: ir@delmarpharma.com / (604) 629-5989. Connect with the Company on [Twitter](#), [LinkedIn](#), [Facebook](#), and [Google+](#). Investor Relations Counsel: Amato & Partners LLC.

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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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To view the original version on PR Newswire, visit <http://www.prnewswire.com/news-releases/delmars-val-083-demonstrates-promise-in-the-treatment-of-non-small-cell-lung-cancer-and-ovarian-cancer-300252824.html>

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