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# FDA Grants Orphan Drug Designation For VAL-083 In Ovarian Cancer

**New Orphan Designation is the Third Awarded to DelMar Pharmaceuticals by FDA Office of Orphan Products Development (OOPD)**

VANCOUVER, British Columbia and MENLO PARK, Calif., April 21, 2016 /PRNewswire/ - [- DelMar Pharmaceuticals, Inc.](#) (OTCQX: DMPI) ("DelMar" and the "Company"), announced today that the FDA Office of Orphan Products Development (OOPD) has granted orphan drug designation for its lead product candidate, VAL-083, in the treatment of ovarian cancer. The investigational drug candidate previously received an orphan designation for glioma and [medulloblastoma](#) in the United States and glioma in Europe.



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.

"We are pleased to receive the designation, which is timely in light of [new data presented this week with supporting the potential for VAL-083](#) in the treatment of ovarian cancer," said Jeffrey Bacha, chairman and CEO of DelMar Pharmaceuticals. "This announcement is representative of the progress we've made in developing VAL-083 which we believe positions the therapy as a viable treatment option for ovarian cancer patients."

DelMar's collaborators from the University of Texas MD Anderson Cancer Center (MD Anderson) presented preclinical data demonstrating that VAL-083 appears to have a distinct mode of action from platinum-based chemotherapies widely used in the treatment of ovarian cancer. In these studies, VAL-083 demonstrated an ability to circumvent cisplatin-resistance in all ovarian cell lines tested.

These new data were presented in a poster entitled, "[Enhanced in vitro activity of dianhydrogalactitol \(VAL-083\) in combination with platinum drugs: Impact of p53 and platinum-resistance](#)," on Monday April 18, 2016 at the annual meeting of the American

Association of Cancer Research.

According to Evaluate Pharma, the market for ovarian cancer therapies is expected to be approximately \$570 million in 2016 and is projected grow to more than \$3.5 billion in 2022. The American Cancer Society estimates that approximately 22,000 women will receive a new diagnosis of ovarian cancer and approximately 14,000 women will die from ovarian cancer in the United States each year. Ovarian cancer ranks fifth in cancer deaths among women, accounting for more deaths than any other cancer of the female reproductive system.

Ovarian cancers are commonly treated with a platinum-based chemotherapy regimen. Initial tumor response rates are relatively high; however, up to 75% of ovarian cancer patients who respond to initial treatment will relapse within approximately 18 months after completing first-line therapy. Median survival in platinum-resistant recurrent ovarian cancer patients ranged from six to nine months in published studies.

"Ovarian cancer represents the latest indication where our current research, combined with historical clinical activity demonstrated in NCI-sponsored clinical trials, supports our strategy to focus our development of VAL-083 as a new treatment option for ovarian cancer patients who have failed or are unlikely to respond to modern chemotherapeutic regimens," said Mr. Bacha. "We look forward to working with the FDA's Office of Orphan Product Development and leading investigators to advance this program alongside our ongoing efforts in glioblastoma and other solid tumors."

### **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 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.

DelMar has been conducting a Phase I/II clinical trial with VAL-083 as a potential new treatment for glioblastoma multiforme (GBM), the most common and aggressive form of brain cancer. DelMar provided an update on this ongoing trial at AACR confirming that results to date support the potential of a VAL-083 to offer a clinically meaningful survival benefit and a promising new treatment option for GBM patients who have failed or are unlikely to respond to currently available chemotherapeutic regimens. The Company anticipates meeting with the FDA in the first half of 2016 to discuss a proposed registration-directed Phase III protocol and data from its current clinical trial with a goal of advancing VAL-083 into registration-directed clinical trials for GBM patients who have failed temozolomide and bevacizumab.

For further information, please visit <http://delmarpharma.com/>; or contact DelMar Pharmaceuticals Investor Relations: [ir@delmarpharma.com](mailto:ir@delmarpharma.com) / (604) 629-5989. Connect with the Company on [Twitter](#), [LinkedIn](#), [Facebook](#), and [Google+](#). Investor Relations Counsel: Amato & Partners LLC.

**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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