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DelMar Pharmaceuticals Presents Overview of VAL-083's Unique Anticancer Mechanism at the European Association of Neuro-Oncology (EANO) Annual Meeting

VANCOUVER, British Columbia, and MENLO PARK, Calif., Oct. 17, 2016 /PRNewswire/ - [DelMar Pharmaceuticals, Inc.](#) (NASDAQ: DMPI) ("DelMar" and the "Company"), a biopharmaceutical company focused on the development and commercialization of new cancer therapies, is pleased to announce that the Company presented additional data regarding VAL-083's unique anti-cancer mechanism on Saturday October 15, 2016 at the [12th Meeting of the European Association of Neuro-Oncology \(EANO\)](#) in Mannheim, Germany.



DelMar's poster presentation can be viewed at <http://www.delmarpharma.com/scientific-publications.html>.

"These data further differentiate VAL-083's mechanism of action against cancer from the current standard of care in the treatment of glioblastoma multiforme (GBM), the most common and aggressive form of brain cancer," said Dr. Dennis Brown, DelMar's Chief Scientific Officer.

Temozolomide, the current front-line therapy generates its anti-tumor activity by methylation of the O6-position of guanine, resulting in a base-pair mismatch which can be lethal to the tumor cell if not repaired. The majority of patients exhibit a high expression of the DNA repair enzyme "MGMT", which readily repairs temozolomide-derived DNA damage leading to tumor resistance and treatment failure. GBM patients failing temozolomide have a very poor prognosis with median survival of 6 – 9 months.

VAL-083 attacks the tumor's DNA at a different location and in a different way, rapidly forming durable cross links at the N7-position of guanine. These cross-links are not repaired by MGMT.

"These cross-links result in double-strand breaks during DNA replication which are more

potent and more difficult for the cell to repair in comparison to the DNA damage conferred by temozolomide. In particular, MGMT does not act against the type of DNA damage resulting from VAL-083 treatment," added Dr. Brown.

"The EANO meeting provided an opportunity to introduce our VAL-083 to European neuro-oncology thought-leaders," said Jeffrey Bacha chairman & CEO of DelMar. Expanding our relationships with key opinion leaders on a global basis will provide opportunities for collaboration as we expand the development of VAL-083 beyond our current focus in the refractory, Avastin-failed population.

"Importantly, poor patient outcomes due to MGMT-mediated chemo-resistance were a consistent theme throughout the conference. Based on our research, we believe VAL-083's unique mechanism and ability to circumvent the tumor's MGMT resistance mechanism may provide a foundational opportunity as a new treatment paradigm," stated Mr. Bacha.

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 has received an orphan drug designation in Europe for the treatment of malignant gliomas and the U.S. FDA Office of Orphan Products has granted an orphan designation to VAL-083 for the treatment of glioma, medulloblastoma and ovarian cancer.

The Company has completed a successful end of Phase II meeting with the US FDA and plans to advance VAL-083 into a pivotal clinical trial for GBM patients following bevacizumab failure. DelMar presented data from its Phase I/II clinical trial in refractory GBM at the 2016 American Association of Clinical Oncology (ASCO) Annual meeting demonstrating that the median survival of 22 patients receiving an assumed therapeutic dose of VAL-083 ($\geq 20\text{mg/m}^2$) was 8.35 months following bevacizumab (Avastin) failure compared to published literature where survival of approximately two to five months has been reported.

DelMar's advanced development program will feature a single multi-center randomized Phase III study measuring survival outcomes compared to a "physicians' choice" control, which, if successful, would serve as the basis for a New Drug Application (NDA) submission for VAL-083. The control arm will consist of a limited number of salvage chemotherapies currently utilized in the treatment of Avastin-failed GBM. The final pivotal trial design will be confirmed with the FDA following further discussions with the Company's clinical advisors.

In addition to the pivotal trial, DelMar also plans to initiate two separate Phase II clinical trials in earlier-stage GBM patients.

- In collaboration with the [University of Texas MD Anderson Cancer Center](#): A non-comparative, biomarker-driven, Phase II study to determine if treatment of MGMT-unmethylated recurrent GBM with VAL-083 or CCNU improves overall survival at 9 months, compared to historical control in bevacizumab naïve patients. (clinicaltrials.gov identifier: NCT02717962)
- In collaboration with [Sun-Yat Sen University](#) and Guangxi Wuzhou Pharmaceutical (Group) Co.: A single arm Phase II clinical trial to confirm the tolerability of DelMar's

dosing regimen in combination with radiotherapy (XRT) and to explore the activity of VAL-083 in newly diagnosed MGMT-unmethylated GBM patients whose tumors are known to express high levels of MGMT.

DelMar believes that data from these clinical trials, if successful, will form the basis of a new paradigm in the treatment for all GBM patients who fail, or whose tumors exhibit features that make them unlikely to respond to, currently available chemotherapy.

In addition to its clinical research in GBM, DelMar believes that its research supports a unique mechanism of action for VAL-083 and that these data support the potential of VAL-083 as a new chemotherapy that may offer improved outcomes in the treatment of GBM and other solid tumors in patients whose tumors have failed or exhibit features that make them resistant to or unlikely to respond to current standard-of-care chemotherapy.

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 intolerant to modern targeted or biologic treatments. The Company's drug in development, VAL-083, is currently undergoing clinical trials in the U.S. as a potential treatment for refractory GBM. 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+](#).

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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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