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## **DelMar Pharmaceuticals to Collaborate with MD Anderson Cancer Center on Development of DelMar's VAL-083 in Brain Cancer**

**- MD Anderson to initiate new clinical studies for the treatment of recurrent GBM -**

VANCOUVER and MENLO PARK, Calif., Jan. 13, 2016 /PRNewswire/ --[DelMar Pharmaceuticals, Inc.](#) (OTCQX: DMPI) ("DelMar" and the "Company") today announced that it has entered into a collaboration with the University of Texas MD Anderson Cancer Center (MD Anderson) to accelerate the clinical development of DelMar's lead anti-cancer candidate, VAL-083, for the treatment of glioblastoma multiforme (GBM), the most common and deadly form of brain cancer.



As part of the collaboration, MD Anderson will initiate a new Phase II clinical study with VAL-083 in patients with GBM at first recurrence/progression, prior to Avastin™ (bevacizumab) exposure. Patients eligible for the study will have recurrent GBM characterized by a high expression of MGMT, the DNA repair enzyme implicated in drug-resistance and poor patient outcomes following current front-line chemotherapy. MGMT promoter methylation status will be used as a validated biomarker for enrollment and tumors must exhibit an unmethylated MGMT promoter for patients to be eligible for the trial.

VAL-083 is a first-in-class small molecule chemotherapy that readily crosses the blood brain barrier. DelMar's research has demonstrated that VAL-083's anti-cancer mechanism is active independent of tumor MGMT status. Approximately 2/3 of GBM patients have tumors with an unmethylated MGMT promoter, which is correlated with resistance to currently available chemotherapy and poor patient outcomes.

"The progress we continue to make with our research shows that VAL-083 may offer advantages over currently available chemotherapies in a number of tumor types," stated Jeffrey Bacha, DelMar's chairman & CEO. "This collaboration will allow us to leverage world-class clinical and research expertise and a large patient population from MD Anderson as we

extend and accelerate our clinical focus to include GBM patients following first recurrence of their disease."

[DelMar recently presented favorable interim data at the 2015 Society for Neuro-Oncology Annual Meeting from its ongoing Phase II clinical trial with VAL-083](#) as a potential "third-line" therapy in GBM patients whose tumors have recurred following treatment with both temozolomide and bevacizumab.

From MD Anderson, the collaboration will be led by Dr. Barbara Jane O'Brien Assistant Professor, Department of Neuro-Oncology, and Marta Penas-Prado, Assistant Professor, Department of Neuro-Oncology,

"We believe that VAL-083's unique cytotoxic mechanism offers promise for GBM patients across the continuum of care as a potential superior alternative to currently available cytotoxic chemotherapies, especially for patients whose tumors exhibit a high-expression of MGMT," added Mr. Bacha.

DelMar also plans to continue ongoing pre-clinical research related to VAL-083's unique mechanism of action with researchers at MD Anderson. DelMar has recently presented data stemming from this research at scientific meetings that suggest that VAL-083 may offer new treatment options for GBM, [non-small cell lung cancer](#), [ovarian cancer](#) and [pediatric medulloblastoma](#).

"We look forward to working with the world-class scientists and clinicians at MD Anderson to accelerate our research bringing us closer to our vision to transform the treatment of patients whose cancers fail or are unlikely to respond to currently available treatments," 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 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.

VAL-083 is a bi-functional DNA N<sup>7</sup> cross-linking agent that crosses the blood-brain barrier that has demonstrated historical clinical activity against a range of cancers, including GBM, in prior NCI-sponsored clinical trials. DelMar has demonstrated that VAL-083 induces phosphorylation of H2AX, a hallmark of double-strand DNA breaks, leading to cell cycle arrest in the late G2/S phase. H2AX is a histone involved in the CHK2 checkpoint activation pathway, a key component of the body's immune response to DNA damage that activates down-stream signaling ultimately resulting in apoptosis (cancer cell death). Additionally, the cytotoxic activity of VAL-083 appears to be less dependent on wild type p53 in comparison to other chemotherapeutic agents. Alteration in p53 has been correlated with poor patient outcomes in GBM. In particular, gain-of-function mutant p53 is strongly associated with a poor prognosis for overall survival in patients with glioblastoma, potentially by increasing expression of MGMT, a DNA repair enzyme that is implicated in chemotherapy resistance to temozolomide and poor outcomes in GBM patients.

[DelMar has previously demonstrated that VAL-083's anti-tumor activity is unaffected by the expression of MGMT.](#) Taken together with historical and recently demonstrated clinical activity, these data suggest a distinct anti-cancer mechanism for VAL-083 which has the potential to overcome chemo-resistance and surpass the standard of care in the treatment of GBM.

DelMar recently announced the completion of enrollment in a Phase II clinical trial of VAL-083 in refractory GBM. Patients have been enrolled 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).

In the Phase I dose-escalation portion of the study, VAL-083 was well tolerated at doses up to 40mg/m<sup>2</sup> using a regimen of daily x 3 every 21 days. Adverse events were typically mild to moderate; no treatment-related serious adverse events reported at doses up to 40 mg/m<sup>2</sup>. Dose limiting toxicity (DLT) defined by thrombocytopenia (low platelet counts) was observed in two of six (33%) of patients at 50 mg/m<sup>2</sup>. Generally, DLT-related symptoms resolved rapidly and spontaneously without concomitant treatment, although one patient who presented with hemorrhoids received a platelet transfusion as a precautionary measure.

Sub-group analysis of data from the Phase I dose-escalation portion of the study suggested a dose-dependent and clinically meaningful survival benefit following treatment with VAL-083 in GBM patients whose tumors had progressed following standard treatment with temozolomide, radiotherapy, bevacizumab and a range of salvage therapies.

Patients in a low dose ( $\leq 5\text{mg/m}^2$ ) 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/m<sup>2</sup> & 40mg/m<sup>2</sup>) sub-group following initiation of VAL-083 treatment. DelMar 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.

#### **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.

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+](#).

#### **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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