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DelMar Pharmaceuticals Presents Data Supporting VAL-083 as a Promising Potential Treatment for Pediatric Brain Tumors

- Preclinical and clinical data support advancement of VAL-083 into a clinical study in pediatric patients with recurrent or resistant medulloblastoma (MB) and high grade gliomas (HGGs) -

VANCOUVER, British Columbia and MENLO PARK, Calif., Nov. 11, 2015 /PRNewswire/ -- DelMar Pharmaceuticals, Inc. (OTCQX: DMPI) ("DelMar" and the "Company"), a biopharmaceutical company focused on the development and commercialization of new cancer therapies, presented data on the potential of VAL-083 (*dianhydrogalactitol*) as a new chemotherapy treatment for malignant pediatric brain tumors.

The Company presented the data in a poster entitled, "*Dianhydrogalactitol (VAL-083) Offers Potential Therapeutic Alternatives in the Treatment of Pediatric Brain Tumors*," at the American Association for Cancer Research (AACR) Advances in Pediatric Research: From Mechanisms and Models to Treatment and Survivorship conference on Tuesday, November 10, 2015.

"We believe that VAL-083 may be an effective chemotherapeutic alternative for pediatric brain tumors," stated Jeffrey Bacha, president & CEO of DelMar Pharmaceuticals. "Based on an analyses of historical clinical trials sponsored by the U.S. National Cancer Institute and DelMar's recent clinical and preclinical data, the Company sought to further investigate the cytotoxic activity of VAL-083 against resistant forms of pediatric medulloblastoma and pediatric high grade gliomas cell lines, *in vitro*."

The data analyses and the *in vitro* study results detailed in the poster demonstrate that:

- VAL-083 has historical activity in childhood refractory medulloblastoma (MB) and glioblastoma multiforme (GBM);
- VAL-083 overcomes MGMT-related temozolomide (TMZ) resistance in GBM cancer

stem cells and non-cancer stem cells cancer stem cells (CSCs) and non-CSCs;
- VAL-083 is active against medulloblastoma cells with SHH characteristics and p53 mutations; and
- VAL-083 in combination with TMZ completely inhibits self-renewal of pediatric GBM cancer stem cells (CSCs).

"The compilation of these data and our recent compelling*in vitro* results in pediatric MB and HGG warrant the further *in vitro* research, which will serve as a basis for our clinical development strategy with VAL-083 in pediatric brain tumors," continued Mr. Bacha. "As the next step, we expect to establish discussions with leading clinical investigators in the field in order to undertake the necessary steps to advance VAL-083 into clinical studies as a potential treatment for children suffering from recurrent medulloblastoma or high grade gliomas."

Poster Summary

Medulloblastoma (MB) is the most common malignant pediatric brain tumor, accounting for 15-30% of all childhood intracranial neoplasms. High grade gliomas (HGG) are much rarer in children than in adults, comprising only 5%-10% of childhood brain tumors. Although multidisciplinary treatment has improved the 5-year survival rates in children significantly, the prognoses for recurrent MB and HGG remain poor with a median overall survival of less than one (1) year. Temozolomide (TMZ) is frequently employed in the treatment of MB and pediatric HGG; however, clinical evidence is lacking and poor outcomes due to high-expression of the repair protein O6-methylguanine-DNA methyltransferase (MGMT), which is correlated with TMZ resistance, have been reported.

VAL-083 is a structurally unique bi-functional alkylating agent, whose cytotoxic activity is due to the formation of DNA cross links at the N7. VAL-083 readily crosses the blood brain barrier and has been shown to accumulate in brain tumor tissue. The mechanism of VAL-083 is believed to be distinct from the mechanisms of other alkylating agents commonly used in the treatment of brain cancer (e.g. temozolomide, cisplatin or BCNU). DelMar has recently shown that VAL-083 overcomes TMZ-resistance and cisplatin-resistance, *in vitro*. VAL-083 has also demonstrated activity against medulloblastoma and glioma cell lines *in vitro*, including treatment-resistant GBM cancer stem cells (CSC).

In historical NCI-sponsored clinical studies, VAL-083 demonstrated clinical activity against medulloblastoma and high-grade gliomas. In these studies VAL-083 was investigated both as a stand-alone therapy and in combination with other chemotherapeutic regimens. VAL-083 demonstrated clinical activity in a range of brain tumor types, including MB and HGG. Additionally, data from one historical Phase II clinical trial in refractory MB, suggests a lack of cross-resistance between VAL-083 and common chemotherapeutic drugs used in MB treatment, and suggests VAL-083 may be valuable in chemo-resistant medulloblastoma and as part of a combination treatment.

More recently, DelMar has shown that VAL-083 demonstrates cytotoxic activity in glioblastoma (GBM) independent of MGMT expression *in vitro* and *in vivo*. Research has also shown that VAL-083 is highly effective against GBM cancer stem cells (CSC) and non-CSC and acts as a radiosensitizer in GBM cell lines, *in vitro*. Additionally, in the Company's has recently reported promising data from its ongoing Phase II clinical trial in adult patients with recurrent GBM.

Summary of Proposed Clinical Trial

DelMar's poster also outlined the company's proposed clinical development strategy. Results of further *in vitro* research will be used to guide clinical strategy for development of VAL-083 as a potential new therapy for treatment of pediatric MB and pediatric HGG. The goal is to stratify patients based on their specific molecular subtype and target VAL-083-responsive difficult-to-treat tumors. However initially, VAL-083 will be tested in recurrent patients with MB or HGG.

"By focusing on 'high-risk molecular' patients stratified based on their molecular subtype, we hope to provide a new treatment option for difficult-to treat pediatric brain tumors such as HGG, and difficult-to-treat medulloblastoma sub-types including SHH patients with p53 mutations and group 3 tumors, ultimately providing a solution to a true unmet medical need," added Mr. Bacha.

Primary goal

- To establish the maximum tolerated dose in children

Secondary goals

- To estimate the efficacy of VAL-083, as measured by objective radiographic response
- To evaluate progression-free survival (PFS) at 6 months
- To evaluate median overall survival (OS)
- To evaluate the safety profile of VAL-083 treatment

The poster presentation and other VAL-083 posters and scientific publications may be found on DelMar's website under http://www.delmarpharma.com/scientific-publications.html.

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 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 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^2 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^2. Dose limiting toxicity (DLT) defined by thrombocytopenia (low platelet counts) was observed in two of six (33%) of patients at 50 mg/m^2. 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 (≤5mg/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^2 & 40mg/m^2) 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.

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

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 / (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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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/delmar-pharmaceuticals-presents-data-supporting-val-083-as-a-promising-potential-treatment-for-pediatric-brain-tumors-300174832.html

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