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DelMar Pharmaceuticals Presents Phase I/II GBM Clinical Trial Data and Outlines Future Clinical Development Plans at ASCO 2016 Annual Meeting

VANCOUVER, British Columbia and MENLO PARK, Calif., June 6, 2016 /PRNewswire/ -- DelMar Pharmaceuticals, Inc. (OTCQX: DMPID) ("DelMar" and the "Company"), a company focused on developing and commercializing proven cancer therapies in new orphan drug indications, presented new data from its recently completed Phase I/II clinical trial of VAL-083 *(dianhydrogalactitol)* at the American Society of Clinical Oncology's (ASCO) Annual Meeting on Saturday, June 4, 2016.

"This year's ASCO meeting was an opportunity to share the aggregate of our research to date with the global cancer research community," stated Jeffrey Bacha, chairman and CEO of DelMar Pharmaceuticals. "Based on our findings related to VAL-083's unique mechanism of action and data from our Phase I/II clinical trial we believe that VAL-083 has the potential to offer a new treatment option for cancer patients whose tumors exhibit features correlated with resistance to currently available chemotherapy."

DelMar's abstract entitled, "Phase I/II Study of Dianhydrogalactitol in Patients with Recurrent Glioblastoma", was presented during the Central Nervous System poster session on Saturday. The poster presentation can be viewed on DelMar's website.

In summary, DelMar's presentation noted:

- VAL-083 attacks cancer cells via a unique mechanism of action which is distinct from other chemotherapies used in the treatment of glioblastoma multiforme (GBM). Specifically, VAL-083 is active independent of MGMT, a DNA repair enzyme which is highly expressed in approximately 2/3 of GBM patients and correlated with resistance to temozolomide, the current front-line chemotherapy in the treatment of GBM. Of patients tested in the DelMar trial, 84% exhibited high MGMT.
- Median survival of 22 patients receiving an assumed therapeutic dose of VAL-083 (≥20mg/m^2) was 8.35 months, suggesting that VAL-083 may offer improved survival

for GBM patients following bevacizumab (Avastin) failure in comparison to currently available salvage therapy. Median survival for VAL-083 treated patients following bevacizumab failure compared with published literature demonstrating survival of approximately three to five months with common salvage therapy regimens.

VAL-083 compared to published literature

Reference	Post Avastin Salvage Therapy	Median Survival from Bevacizumab Failure
Rahman *(2014)*	nitrosourea	4.3 months
Mikkelson *(2011)*	TMZ + irinotecan	4.5 months
Lu *(2011)*	dasatinib	2.6 months
Reardon *(2011)*	etoposide	4.7 months
Reardon *(2011)*	TMZ	2.9 months
Iwomoto *(2009)*	various	5.1 months
DelMar Trial	***VAL-083***	**8.35 months**

- A dose of 40 mg/m^2/day VAL-083 administered on the first three days of every three week cycle is well tolerated in refractory GBM patients and has been selected for study in subsequent clinical trials.

DelMar recently announced the completion of a successful end of Phase II meeting with the US FDA and its plans to advance VAL-083 into a pivotal clinical trial for GBM patients whose tumors have recurred following front-line therapy and second line treatment with bevacizumab.

DelMar's advanced development program will feature a single randomized Phase 3 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.

- A randomized, non-comparative, biomarker-driven, Phase 2 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)
- A single arm Phase 2 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.

"We wish to thank the patients, their families, and the physicians who participated in our Phase I/II clinical trial," said Mr. Bacha. "We are pleased to be advancing VAL-083 into these new trials that we believe, if successful, will serve as the basis for a new treatment paradigm in the treatment of GBM."

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 USFDA'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 conducted 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. Patients were 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) *(clinicaltrials.gov identifier: NCT01478178)*. DelMar announced the completion of enrollment in a Phase II expansion cohort in September, 2015.

About Glioblastoma Multiforme (GBM)
Glioblastoma multiforme (GBM) is the most common and most malignant form of brain cancer. Approximately 15,000 people are diagnosed with GBM each year in the U.S., with similar incidence in Europe. Standard of care is surgery, followed by either radiation therapy, or radiation therapy combined with temozolomide. Approximately 60 percent of GBM patients treated with temozolomide experience tumor progression within one year. More than half of glioblastoma patients will fail the currently approved therapies and face a very poor prognosis.

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 intollerant 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+.

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-phase-iii-gbm-clinical-trial-data-and-outlines-future-clinical-development-plans-at-asco-2016-annual-meeting-300279959.html

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