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DelMar Pharmaceuticals Expands Glioblastoma Clinical Trial

Opening of UC San Francisco Clinical Site Expected to Accelerate Development of VAL-083

VANCOUVER, BC and MENLO PARK, CA -- (Marketwired) -- 07/31/13 -- [DelMar Pharmaceuticals, Inc.](#) (OTCQB: DMPI) ("DelMar") announced the opening of its third clinical trial site at the Brain Tumor Center at University of California, San Francisco (UCSF). DelMar is currently conducting a Phase I/II dose-escalation study designed to assess the safety and activity of VAL-083 as a potential treatment for brain cancer patients suffering from glioblastoma multiforme (GBM) who have failed standard therapies and have no viable treatment options.

Jeffrey Bacha, DelMar's president & CEO said, "Opening UCSF as the first West Coast clinical site for our VAL-083 glioblastoma clinical trial is a key step in our strategy to increase patient access. This new site will also help accelerate the overall development of VAL-083 as a much-needed, new therapy for refractory glioblastoma multiforme, the most common and aggressive form of brain cancer."

The Brain Tumor Center at UCSF is one of the largest and most comprehensive programs for brain tumor treatment in the U.S., and it includes the Division of Neuro-oncology, the Brain Tumor Research Center, and the Division of Translational Research. DelMar also has clinical trial sites at the Sarah Cannon Research Institute in Nashville, Tennessee and at a second center in Sarasota, Florida.

In June this year, DelMar presented interim clinical data from the ongoing clinical trial at the American Society of Clinical Oncology (ASCO) annual meeting. Highlights of DelMar's ASCO data include:

- VAL-083 therapy is well tolerated by patients at doses studied to date;
- While doses tested to date were well below those used in historical clinical studies, 25% of GBM patients and 17% of secondary-progressive brain cancer patients showed stable disease or tumor regression in response to VAL-083 treatment. These patients had failed prior therapy before being treated with VAL-083;
- Maximum tolerated dose (MTD) has not yet been reached; continued dose escalation and accelerated development of VAL-083 in GBM is warranted;
- Pharmacokinetic analysis shows dose-dependent increase in plasma exposure following doses of VAL-083, which suggests higher dosing is likely to result in stronger

tumor response.

About VAL-083

VAL-083 represents a 'first-in-class' small-molecule chemotherapeutic. VAL-083 has been assessed in multiple NCI-sponsored clinical studies in various cancers including lung, brain, cervical, ovarian tumors and leukemia. Published pre-clinical and clinical data suggest that VAL-083 may be active against a range of tumor types. VAL-083 is approved as a cancer chemotherapeutic in China for the treatment of chronic myelogenous leukemia and lung cancer.

Based on published research, the mechanism of action of VAL-083 is understood to be a bi-functional alkylating agent; however, the functional groups associated with alkylating events has been shown to differ from other alkylating agents used in the treatment of GBM.

VAL-083 has previously demonstrated activity in cyclophosphamide, BCNU and phenylalanine mustard resistant cell lines and no evidence of cross-resistance has been encountered in published clinical studies. Based on the presumed alkylating functionality of VAL-083, published literature suggests that DNA repair mechanisms associated with Temodar[®] and nitrosourea resistance, such as O6-methylguanine methyltransferase (MGMT), may not confer resistance to VAL-083.

VAL-083 readily crosses the blood brain barrier where it maintains a long half-life in comparison to the plasma. Published preclinical and clinical research demonstrates that VAL-083 is selective for brain tumor tissue.

VAL-083 has been assessed in multiple studies as chemotherapy in the treatment of newly diagnosed and recurrent brain tumors. In general, tumor regression was achieved following therapy in greater than 40 percent of patients treated and stabilization was achieved in an additional 20 to 30 percent. In published clinical studies, VAL-083 has previously been shown to have a statistically significant impact on median survival in high-grade gliomas when combined with radiation versus radiation alone.

The main dose-limiting toxicity related to the administration of VAL-083 in previous clinical studies was myelosuppression. No significant hepatic, renal or pulmonary toxicity has been reported in the literature or overseas commercial experience.

About Glioblastoma Multiforme (GBM)

GBM is the most common and most malignant form of brain cancer. Of the estimated 17,000 primary brain tumors diagnosed in the U.S. each year, approximately 60 percent are gliomas. Attention was drawn to this form of brain cancer when Senator Ted Kennedy was diagnosed with glioblastoma in 2008 and ultimately died from the disease fifteen months later.

Newly diagnosed patients suffering from GBM are initially treated through invasive brain surgery, although disease progression following surgical resection is nearly 100 percent. Temodar in combination with radiation is the front-line therapy for GBM following surgery. Temodar currently generates more than US\$950 million annually in global revenues

primarily from the treatment of brain cancer.

Approximately 60 percent of GBM patients treated with Temodar[®] experience tumor progression within one year. Avastin[®] has been approved for the treatment of GBM in patients failing Temodar[®]. According to the Avastin[®] label, approximately 20 percent of patients failing Temodar[®] respond to Avastin[®] therapy. Analysts anticipate annual Avastin[®] revenues for the treatment of brain cancer may reach US\$650 million by 2016.

Approximately 48 percent of patients who are diagnosed with GBM will fail both front-line Temodar[®] therapy and Avastin[®]. DelMar estimates that the market for treating GBM patients the post-Avastin failure exceeds US\$200 million annually in North America.

About the VAL-083 Clinical Trial

The Phase I/II study is an open-label, single arm dose-escalation study designed to evaluate the safety, tolerability, pharmacokinetics and anti-tumor activity of VAL-083 in patients with histologically confirmed initial diagnosis of primary WHO Grade IV malignant glioma (GBM), now recurrent. Patients with prior low-grade glioma or anaplastic glioma are eligible, if histologic assessment demonstrates transformation to GBM.

GBM patients must have been previously treated for GBM with surgery and/or radiation, if appropriate, and must have failed both Avastin and Temodar, unless either or both are contra-indicated.

Response to therapy and disease progression will be evaluated by MRI prior to each treatment cycle. An initial phase of the study will involve dose escalation cohorts until a maximum tolerated dose (MTD) is established in the context of modern care. Once the modernized dosing regimen has been established, additional patients will be enrolled at the MTD (or other selected optimum dosing regimen).

DelMar is conducting the study at three clinical sites including the University of California, San Francisco, the Sarah Cannon Research Institute in Nashville, Tennessee and at the Florida Cancer Specialists & Research Institute in Sarasota, Florida.

Please refer to clinicaltrials.gov identifier NCT01478178 for further details on this clinical trial or visit: <http://www.clinicaltrials.gov/ct2/show/NCT01478178?term=VAL--083&rank=1>

About DelMar Pharmaceuticals

DelMar Pharmaceuticals was founded in 2010 to develop and commercialize proven cancer therapies in new orphan drug indications where patients are failing modern targeted or biologic treatments. The Company's lead asset, VAL-083, is currently undergoing clinical trials in the United States as a potential treatment for refractory glioblastoma multiforme (GBM), the most common and aggressive form of brain cancer. VAL-083 benefits from extensive clinical research sponsored by the U.S. National Cancer Institute, and is currently approved for the treatment of chronic myelogenous leukemia (CML) 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.

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. We do not undertake to update these forward-looking statements made by us.

UC Disclaimer

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