

# DelMar Pharma Presents Encouraging Data From Ongoing Phase I/II GBM Clinical Trial With VAL-083

VANCOUVER, British Columbia and MENLO PARK, Calif., April 10, 2013 /PRNewswire/ - DelMar Pharmaceuticals, Inc. (OTCQB: DMPI) today announced additional positive interim data from an ongoing Phase I/II clinical trial of VAL-083 in patients with recurrent glioblastoma multiforme (GBM) or progressive secondary brain tumor.

The data are being presented at the *American Association for Cancer Research (AACR) Annual Meeting* in Washington, D.C. during a clinical poster session entitled, "A Phase I/II Study of VAL-083 in Patients with Recurrent Malignant Glioma or Progressive Secondary Brain Tumor."

### Information regarding the presentation:

Session Title:

Phase II and Phase III Adult Clinical Trials

Session

Wednesday, April 10, 2013, 8:00 am - 12:00 pm

Time:

Poster Title:

Presentation: 4672

"A Phase I/II Study of VAL-083 in Patients with Recurrent Malignant Glioma or Progressive Secondary Brain

Tumor"

Location: Hall A-C, Poster Section 2, Washington Convention Center

"These data represent continued progress to modernize the dosing regimen with VAL-083 as a potential treatment for recurrent brain tumors, including GBM, the most common and aggressive form of brain cancer. We are optimistic that we will continue to gather positive data as we reach higher doses in our clinical trial," said Jeffrey Bacha, President and Chief Executive Officer of DelMar Pharmaceuticals.

The data presented are part of an ongoing Phase I/II open-label, single arm dose-escalation study. Three dose cohorts were completed without reaching dose-limiting toxicity (DLT), and no drug-related adverse effects were detected. VAL-083 was seen to be safe and well tolerated at tested doses in patients who have failed other available therapies. In particular, GBM patients in the trial must have failed both bevacizumab (Avastin<sup>®</sup>) and temozolomide (Temodar<sup>®</sup>), unless either or both are contra-indicated.

Pharmacokinetic data reported by the Company demonstrated a dose response as expected based on observations reported in the historical literature. In addition, the Company previously presented data supporting the activity of VAL-083 against GBM tumors expressing resistance to the current front-line therapy, Temodar.

Mr. Bacha continued, "While these data are preliminary in nature, we have seen an overall response rate of 33.3%, where tumor growth had stabilized or regressed, in patients that had failed other therapies. We believe these data along with the differentiated mechanism of action of VAL-083, which supports potential activity when other therapies face tumor resistance, provides strong rationale for the further development of VAL-083."

Mr. Bacha further noted that doses of VAL-083 within the Company's proposed target doses had achieved reported response rates as high as 40 percent in historical GBM clinical trials sponsored by the U.S. National Cancer Institute (NCI).

"We look forward to continuing to work with our clinical investigators toward determining an optimal dosing regimen for future registration trials and to the potential opportunity of offering patients a valuable new treatment option for these aggressive brain cancers," added Mr. Bacha.

The company's permanent AACR abstract (#4672) can be viewed by clicking here or searching the following link <a href="http://www.abstractsonline.com/Plan/AdvancedSearch.aspx">http://www.abstractsonline.com/Plan/AdvancedSearch.aspx</a>

### 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 bifunctional 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 phenylanine 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 06-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 and ultimately died from it.

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 therapy and Avastin. DelMar Pharma 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 Study

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. Patients with secondary brain tumors due to CNS metastases are also eligible for the study.

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 Pharma is conducting the study under the direction of Dr.Howard Burris at the

Sarah Cannon Research Institute in Nashville, Tennessee with a second center in Sarasota, Florida.

Please refer to <u>clinicaltrials.gov</u> identifier NCT01478178 for further details on this clinical trial.

For further details on DelMar's clinical trial please visit: <a href="http://www.clinicaltrials.gov/ct2/show/NCT01478178?term=VAL--083&rank=1">http://www.clinicaltrials.gov/ct2/show/NCT01478178?term=VAL--083&rank=1</a>

## **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 U.S. as a potential treatment for refractory glioblastoma multiforme, 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 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.

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