

May 16, 2014



DelMar Pharmaceuticals Updates VAL-083 Glioblastoma Clinical Trial Progress

30mg/m² dose cohort had been completed; enrollment of 40mg/m² cohort has been initiated

Interim clinical data to be presented at ASCO on May 31, 2014

VANCOUVER, British Columbia and MENLO PARK, Calif., May 16, 2014 /PRNewswire/ - [DelMar Pharmaceuticals, Inc.](#) (OTCQB: DMPI) ("DelMar") is pleased to provide an update on the company's ongoing Phase I/II clinical trial for VAL-083 in recurrent glioblastoma multiforme (GBM).

DelMar has completed enrollment of VAL-083 dose Cohort 6 and advanced to Cohort 7.

DelMar most recently presented VAL-083 interim clinical data in April 2014 at the 105th Annual Meeting of the American Association for Cancer Research (AACR). At that time, it was announced that enrollment of Cohort 6 (30mg/m²) had been completed and observations of safety and drug activity were ongoing.

A mandatory safety observation period for Cohort 6 has been completed. VAL-083 was well tolerated by patients treated at the 30mg/m² dose with no significant drug-related adverse events or dose limiting toxicity (DLT). The maximum tolerated dose (MTD) for VAL-083 has not yet been achieved. The Company has now opened Cohort 7 (40mg/m²) for enrollment.

Pharmacokinetic analysis and evaluation of tumor response from patients in Cohort 6 are ongoing. DelMar will present these data and available data from Cohort 7 during the Central Nervous System Tumor Session at the 50th Annual Meeting of the American Society of Clinical Oncology (ASCO), which is being held May 30th to June 3rd, 2014 at the McCormick Place Convention Center in Chicago. The Company's permanent ASCO abstract (#TPS2109) can be viewed [by clicking here](#) or searching <http://abstracts2.asco.org/>.

Previous VAL-083 clinical trials sponsored by the U.S. National Cancer Institute (NCI) reported promising safety and efficacy data for the treatment of GBM. In the NCI-sponsored studies, a cumulative dose of 125mg/m² delivered in a 33 day cycle in combination with radiation was demonstrated to be superior to radiation alone (Eagan et al. 1979). In a comparative 33-day cycle, Cohort 7 of DelMar's dosing regimen will deliver a total of 240mg/m² taking advantage of substantially higher drug concentration and exposure to the tumor.

"Advancing to the 40mg/m² dose cohort is an important clinical milestone in the development of VAL-083," said Jeffrey Bacha, president & CEO of DelMar Pharmaceuticals. "We have now successfully demonstrated that we can deliver both a higher concentration and higher exposure in comparison to the NCI regimen. We believe this, combined with historical data from the NCI demonstrating activity in the treatment of GBM, position VAL-083 as a promising new treatment option for GBM patients who have failed other available therapies."

About VAL-083

VAL-083 represents a first-in-class, small-molecule chemotherapeutic with a unique mechanism of action. In more than 40 Phase 1 and 2 clinical studies sponsored by the U.S. National Cancer Institute (NCI), VAL-083 demonstrated promising activity against a number of cancers including lung, brain, cervical, ovarian tumors and leukemia. VAL-083 is approved in China for the treatment of chronic myelogenous leukemia and lung cancer and has received orphan drug designation in Europe and the U.S. for the treatment of gliomas. DelMar previously presented *in vitro* data demonstrating that VAL-083's unique mechanism of action is unaffected by the expression of MGMT, a DNA repair enzyme that causes chemotherapy resistance to Temodar® (temozolomide). Temodar is currently the standard front-line therapy for the treatment of glioblastoma multiforme (GBM), the most common and aggressive form of brain cancer. DelMar believes that these data, in conjunction with VAL-083's historical activity, establish the drug's potential to provide a viable treatment option for patients suffering from refractory and newly-diagnosed GBM.

About the Phase I/II VAL-083 Dose Escalation Trial

DelMar's 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 recurrent GBM. The study is currently enrolling at three clinical sites in the United States: The University of California, San Francisco (UCSF); The Sarah Cannon Cancer Research Institute (SCRI) in Nashville, TN and the SCRI affiliate site at the Florida Cancer Specialists in Sarasota, FL.

Patients in the trial must have been previously treated for GBM with surgery and/or radiation and must have failed both Avastin® and Temodar®, unless either or both are contra-indicated. Subject to continued progress, DelMar anticipates completing the dose-escalation portion of its current clinical trial in mid-2014. The goal of the dose-escalation portion of the trial is to determine an appropriate dosing regimen for advancement into future registration-directed trials.

Further information regarding DelMar's clinical trial can be found at <http://www.clinicaltrials.gov/ct2/show/NCT01478178?term=val-083&rank=1>

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 glioblastoma each year in the United States, with similar incidence in Europe. Standard of care is surgery, followed by radiation therapy or combined radiation therapy and chemotherapy with temozolomide.

GBM has a poor prognosis and only modest improvements in therapy have been made over

the past 25 years. Median survival for newly diagnosed patients is less than two years and approximately 60 percent of GBM patients treated with the standard front-line temozolomide regimen experience tumor progression within one year. Patients who fail the currently approved therapies have limited treatment options and a very poor prognosis, with a median survival of 3 to 6 months.

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 recurrent 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 (NCI), 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.

SOURCE DelMar Pharmaceuticals, Inc.