

August 19, 2014



# **DelMar Pharmaceuticals Provides Update on Glioblastoma Clinical Trial and Results of Warrant Tender Offer**

**VAL-083 Phase I/II VAL-083 clinical trial advances to 50mg/m<sup>2</sup> cohort**

**Company raises an additional \$2.9 million in non-dilutive financing through warrant exercise**

VANCOUVER, British Columbia and MENLO PARK, Calif., Aug. 19, 2014 /PRNewswire/ - [DelMar Pharmaceuticals, Inc.](#) (OTCQB: DMPI) ("DelMar" "the company") announced today a protocol amendment to allow for expanded dosing in its VAL-083 clinical trial had been filed with the U.S. Food and Drug Administration (FDA) and that a new cohort of a new 50mg/m<sup>2</sup> has been opened at three clinical trial sites in the United States. The company also confirmed that gross proceeds of US\$2.9 million have been raised through warrant exercise in two separate closings. These funds provide sufficient working capital to fund DelMar's current operations, including its glioblastoma clinical trial, through at least December 2015.

One of three glioblastoma multiforme (GBM) patients in the most recent (40mg/m<sup>2</sup>) cohort and one of three GBM patients in the previous (30mg/m<sup>2</sup>) cohort exhibited stable disease after one or two cycles of treatment with VAL-083. No drug-related serious adverse events or dose limiting toxicities (DLTs) have been detected and a maximum tolerated dose (MTD) has not been reached at doses up to 40 mg/m<sup>2</sup>.

The company plans to present detailed results at scientific meetings during the second half of 2014.

Jeffrey Bacha, president and CEO of DelMar stated, "Patients being enrolled in our current clinical trial have a growing brain tumor that has failed to respond to any other approved treatment. The correlation between tumor progression and death in this patient population is well documented; therefore, our interim results demonstrating that, in some patients at doses studied to date, VAL-083 can either stabilize disease progression by halting tumor growth (as measured by RANO criteria) or shrink the tumor is expected to result in longer patient survival and improved quality of life. We anticipate enhanced response rates as we progress to higher doses and keep patients on treatment longer during future registration-directed clinical trials."

**Avoiding Chemotherapy Resistance: VAL-083 MOA Is Unaffected by MGMT Expression**

VAL-083 is a first-in-class small molecule chemotherapy that was studied in previous clinical

trials sponsored by the U.S. National Cancer Institutes (NCI). In NCI-sponsored clinical trials, VAL-083 demonstrated activity against a range of tumor types, including GBM. DelMar's data suggest that the tumor-killing mechanism of VAL-083 is distinct from other chemotherapies approved for the treatment of GBM and therefore are not subject to resistance by mechanisms such as MGMT, which are believed to cause the majority of patients to fail chemotherapies available for treatment today.

DelMar first presented data demonstrating the activity of VAL-083 against patient-derived MGMT-expressing tumors that are resistant to other chemotherapies approved for the treatment of GBM at the 2012 Annual Meeting of the American Association of Cancer Research (AACR). Details of the company's scientific presentations can be found at: <http://www.delmarpharma.com/products/publications/>

### Improved Safety and Tolerability Profile of VAL-083 Allows for Higher Dosing

DelMar previously announced that the company had received a notice of allowance from the FDA enabling the company to implement a more rapid dose-escalation scheme in our GBM study. The revised dosing regimen was allowed by the FDA following an extensive safety review of patients treated prior to that date. This latest protocol amendment, which is based on analysis of the safety and tolerability of VAL-083 delivered under DelMar's modernized dosing regimen, allows dosing at higher doses than originally anticipated.

Mr. Bacha added, "The use of many cancer drugs is limited by toxicity and a narrow therapeutic window. We are pleased that the hypothesis behind our modernized dosing regimen appears to be achieving an improved systemic safety profile while at the same time delivering substantially higher doses of VAL-083 compared to previous clinical trials sponsored by the U.S. National Cancer Institutes and other international studies."

Dose Escalation Scheme (mg/m <sup>2</sup> )		Patients Treated	Status	Cumulative dose in 33-day cycle (comparison to NCI historical regimen of 125mg/m <sup>2</sup> per cycle)
Original	Revised*			
1.5	1.5	3	Completed – No DLT	9 mg/m <sup>2</sup>
3.0	3.0	4**	Completed – No DLT	18 mg/m <sup>2</sup>
5.0	5.0	10**	Completed – No DLT	30 mg/m <sup>2</sup>
10.0	10.0	3	Completed – No DLT	60 mg/m <sup>2</sup>
15.0	20.0	3	Completed – No DLT	120 mg/m <sup>2</sup>
20.0				
25.0	30.0	3	Completed – No DLT	180 mg/m <sup>2</sup>
30.0				
40.0	40.0	3	Completed – No DLT	240 mg/m <sup>2</sup>
na	50.0	3 (planned)	Enrollment Ongoing	300 mg/m <sup>2</sup>
na	60.0	3 (planned)	To be initiated subject to evaluation of 50mg/m <sup>2</sup> dose	360 mg/m <sup>2</sup>

\*Revised based on discussions with FDA

\*\*Cohorts 2 and 3 were expanded to allow for patient demand and to gather additional data on CNS metastases patients.

"We are now delivering doses of VAL-083 substantially higher than were achieved in the original NCI-sponsored clinical trials. Our modernized dosing regimen takes advantage of improved side-effect management and new knowledge of the pharmacokinetic and toxicity profile of VAL-083. Our strategy to 'hit the tumor harder more often' is allowing us to achieve higher levels of drug at the tumor-site, which we believe will result in significant clinical benefit for GBM patients who currently have no viable treatment options," said Mr. Bacha.

## **VAL-083 Targets a Significant Unmet Medical Need in Refractory Glioblastoma**

DelMar plans to advance clinical trials with VAL-083 as a potential treatment for GBM patients who have failed therapy with both Temodar® and Avastin®. Currently, there is no available or approved therapy for these patients and their prognosis is very poor with a life expectancy of only weeks to months. DelMar is currently conducting a Phase I/II clinical trial at three centers: The Brain Tumor Center at University of California, San Francisco (UCSF), The Sarah Cannon Cancer Research Center (SCRI) in Nashville, Tenn., and the SCRI affiliate site at the Florida Cancer Specialist Research Institute in Sarasota, Fla. Details of the clinical trial can be found at [http://www.delmarpharma.com/GBM\\_clinical\\_trial/](http://www.delmarpharma.com/GBM_clinical_trial/)

Mr. Bacha reiterated, "The goal of the current Phase I/II clinical trial is to reestablish the maximum tolerated dose of VAL-083 under our modernized dosing regimen for advancement into registration directed trials in the United States as a potential new therapy for the treatment of refractory GBM as soon as possible."

## **DelMar Is Advancing VAL-083 Toward Pivotal Clinical Trials for Refractory Glioblastoma**

The final dose for advancement into registration-directed clinical trials will be based on the safety and tolerability of VAL-083 in refractory GBM patients. Based on historical precedent, DelMar anticipates that the registration trial will be a Phase II open-label design with radiographic response (as measured by RANO criteria) and overall survival as the primary endpoints. The size, design and timing of initiation of the registration-directed clinical trial will depend on completion of the current dose-escalation study and discussions with the company's clinical advisors and the FDA. DelMar expects that data from the registration-directed trial will form the basis of the company's application for FDA approval of VAL-083 as a potential new therapy for patients with refractory glioblastoma.

Mr. Bacha also stated, "We wish to thank those of our warrant holders who took advantage of our recent tender offer. We are always focused on maintaining a strong balance sheet to fund our research and commercialization efforts and your ongoing support through exercise of warrants has enabled us to access an additional \$2.9 million in non-dilutive capital and positioned us to fund our current operations through at least the end of 2015. Exercise of these warrants has also substantially reduced the derivative liability associated with the warrants, which is an important step toward meeting certain requirements to list our shares on a senior stock exchange in the United States."

Details of the Warrant Tender Offer and related transactions can be found on the company's website at: <http://ir.delmarpharma.com/all-sec-filings#>.

## **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. DelMar's scientific presentations can be viewed on the company's website at [www.delmarpharma.com](http://www.delmarpharma.com).

### **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.*

For further information, please visit [www.delmarpharma.com](http://www.delmarpharma.com)

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