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DelMar Pharmaceuticals Presents Interim Phase 1/2 Clinical Data for VAL-083 in Glioblastoma at Society for Neuro-Oncology Annual Meeting

VANCOUVER, British Columbia and MENLO PARK, Calif., Nov. 22, 2013 /PRNewswire/ -- DelMar Pharmaceuticals, Inc. (OTCQB: DMPI) ("DelMar" and "DelMar Pharma") today announced the presentation of interim data from a Phase 1/2 clinical trial for VAL-083 in recurrent glioblastoma (GBM) at the 4th Quadrennial Meeting of the World Federation of Neuro-Oncology (WFNO) being held in conjunction with the 18th Annual Society for Neuro-Oncology (SNO) meeting in San Francisco. Enrollment in the first four cohorts of the VAL-083 trial has been completed with no significant adverse events or dose limiting toxicity (DLT) observed. Twenty five percent of patients evaluated in Cohorts 1-3 exhibited stable disease or tumor-regression and improved disease symptoms. Evaluation and clinical observations of Cohort 4 is ongoing.

"The fact that we are seeing evidence of clinical activity against refractory GBM at this stage is very promising," said Jeffrey Bacha, president & CEO of DelMar Pharmaceuticals. "VAL-083 is safe and well-tolerated by patients at the doses tested to date, and based on historical data, we anticipate seeing stronger patient benefit and tumor responses as we achieve higher doses."

DelMar's Phase 1/2 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. 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.

Details of the presentation:

- Maximum tolerated dose (MTD) has not yet been reached.

- Enrollment of Cohort 5 (20mg/m2) is expected in December 2013, subject to completion of mandated safety observation period with Cohort 4 (10mg/m^2).

- Pharmacokinetic analysis demonstrates a dose-dependent plasma exposure.

The poster entitled "*Phase I/II study of VAL-083 in patients with recurrent malignant glioma or progressive-secondary brain tumor*," will be presented today from 7 p.m. to 9 p.m.

In August, DelMar received notice of allowance from the U.S. Food and Drug Administration

(FDA) that will enable the company to alter the dose-escalation of its ongoing Phase 1/2 of VAL-083 in refractory glioblastoma multiforme (GBM) patients. After an extensive safety review of patients treated to date, the FDA allowed the revised dosing regimen detailed in the following chart, which enables the trial to reach higher doses and complete the dose-escalation portion of the clinical trial more quickly. The revised dosing scheme also permits dosing above 30mg/m2 if VAL-083 is safe and well tolerated at that dose.

Dose Escalation Scheme (mg/m^2)		**Patients Treated**	**Status**
Original	**Revised**		
1.5	**1.5**	3	Completed – No DLT
3.0	**3.0**	4*	Completed – No DLT
5.0	**5.0**	10*	Completed – No DLT
10.0	**10.0**	3	*No DLT***
15.0			
20.0	**20.0**	3	*Enrollment scheduled Dec*
25.0		*(planned)*	*2013*
30.0	**30.0**	3 *(planned)*	*To be initiated subject to no DLT in 20mg/m^2 dose*

**Cohorts 2 and 3 were expanded to allow for patient demand*

and to gather additional data on CNS metastases patients.

*** Observation period for final patient in this cohort ongoing*

"From previous controlled clinical trials sponsored by the U.S. National Cancer Institute

(NCI), we have seen promising safety and efficacy data for VAL-083 in glioblastoma," said Mr. Bacha. "With our accelerated dose escalation plan compared to the NCI's dosing schedule, we expect to soon be delivering higher doses of VAL-083 and doing so more often."

Mr. Bacha added, "Although accelerating dose escalation is not expected to significantly alter the duration of the trial, we will treat fewer patients at sub-optimal doses and reach doses more likely to achieve meaningful patient benefit in a more cost efficient manner. Importantly, we are proceeding on track to complete dose escalation and advance VAL-083 toward registration directed trials in refractory glioblastoma in the first half of 2014."

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 Phase 2 clinical studies sponsored by the National Cancer Institute (NCI), VAL-083 has shown safety and efficacy in treating 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. As a potential treatment for glioblastoma, VAL-083's mechanism of action is unaffected by the expression of MGMT, a DNA repair enzyme that causes chemotherapy resistance to front-line treatment with Temodar (temozolomide). DelMar is currently studying VAL-083 in a Phase 1/2 clinical trial for patients with refractory glioblastoma multiforme patients.

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 U.S., with similar incidence in Europe. Standard of care is surgery, followed by radiation therapy or combined radiation therapy and chemotherapy 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.

About DelMar Pharmaceuticals

Del Mar 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 (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.

For further information, please visit **www.delmarpharma.com.**

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