

## **DEL MAR PHARMACEUTICALS INITIATES GLIOBLASTOMA CLINICAL TRIAL**

VANCOUVER, BRITISH COLUMBIA (Marketwire – October 25, 2011) DelMar Pharmaceuticals today announced the initiation of the Company’s planned clinical trial with its lead drug candidate, VAL-083, for the treatment of refractory glioblastoma multiforme (GBM).

The Del Mar Pharma sponsored study has been initiated under the direction of Dr. Howard Burris at the Sarah Cannon Research Institute in Nashville, Tennessee. In September 2011, the Company announced that the United States FDA had granted notice of allowance for the trial. The Company has received clearance from the site’s Institutional Review Board and completed site initiation activities, including delivery of study drug to the site. Patients are now actively being screened and eligible patients will be enrolled in the study.

“We are pleased to be advancing this important potential therapy to the next step toward offering a new treatment option to patients suffering from GBM, the most common and aggressive form of brain cancer,” stated Jeffrey Bacha, Del Mar Pharma’s President & CEO.

Of the estimated 17,000 primary brain tumors diagnosed in the United States each year, approximately 60% are gliomas. Attention was drawn to this form of brain cancer when Senator Ted Kennedy was diagnosed with GBM 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%. Temozolomide (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% of GBM patients treated with Temodar® experience tumor progression within one year. Bevacizumab (Avastin®) has been approved for the treatment of GBM in patients failing Temodar®. According to the Avastin® label, approximately 20% 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% 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 after Avastin failure exceeds US\$200 million annually in North America.

Mr. Bacha will be presenting an overview of VAL-083 and discussing the Company’s development and commercialization strategy at 10:30 AM on October 25<sup>th</sup>, 2011 during the 10<sup>th</sup> Annual BIO Investor Forum being held in San Francisco, California.

### **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 solid tumors, including 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 and mechanism of VAL-083 has been shown to differ from other alkylating agents used in the treatment of GBM.

VAL-083 has 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% of patients treated and stabilization was achieved in an additional 20% - 30%. 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 vs. 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 the Clinical Study**

The Phase I/II study is be 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 must have been previously treated for GBM with surgery, and/or radiation, if appropriate, and must have failed both Bevacizumab (Avastin<sup>®</sup>) and temozolomide (Temodar<sup>®</sup>), unless either or both are contra-indicated.

Response to therapy and disease progression will be evaluated magnetic resonance imaging (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).

Further details of the study will be made available on the company's website at [www.delmarpharma.com](http://www.delmarpharma.com) and on [www.clinicaltrials.gov](http://www.clinicaltrials.gov).



### **About DelMar Pharma**

Del Mar Pharmaceuticals (BC) Ltd. 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. Our lead asset, VAL-083, benefits from extensive clinical research sponsored by the US National Cancer Institute, and is currently approved as a cancer chemotherapeutic overseas.

*For further information, please visit [www.delmarpharma.com](http://www.delmarpharma.com) or contact Jeffrey A. Bacha, President & CEO (604) 629-5989*