DEL MAR PHARMACEUTICALS RECEIVES FDA IND APPROVAL TO BEGIN CLINICAL TRIALS WITH A NEW BRAIN CANCER TREATMENT

VANCOUVER, BRITISH COLUMBIA (Marketwire – September 6, 2011) DelMar Pharma today announced that its investigational new drug (IND) application has been allowed by the United States Food and Drug Administration (FDA). The Company is now able to initiate its planned clinical trial with its lead drug candidate VAL-083 for the treatment of refractory glioblastoma multiforme (GBM).

VAL-083 represents a first-in-class bi-functional alkylating agent. The drug benefits from prior extensive clinical research sponsored by the United States National Cancer Institute (NCI), and is approved as a cancer chemotherapeutic in China for the treatment of chronic myelogenous leukemia and solid tumors, including lung cancer. Pre-clinical and clinical studies sponsored by the NCI suggest that VAL-083 may have activity against a range of tumor types, including glioblastoma multiforme (GBM), the most common and aggressive form of brain cancer

The FDA has completed its review of the Company's submissions and concluded that the clinical trial may be initiated.

The clinical trial is a dose-escalating study that will evaluate the safety, tolerability and anti-tumor activity of VAL-083 in GBM patients who have failed front line therapy with Temodar™ and second-line therapy with Avastin™. According to published data, approximately half of patients diagnosed with GBM will fail both front and second line therapy. Currently, there are no approved treatments for these patients.

Jeffrey Bacha, DelMar Pharma's President & CEO said, "The FDA's acceptance of our IND represents a major milestone. We are very pleased to be able to initiate clinical studies with VAL-083."

The Company will now proceed with clinical site initiation and plans to begin patient recruitment activities during the fall of 2011. Further details on the clinical trial will be posted on the Company's website once patient recruitment commences.

"This clinical trial is designed to bring a previously promising drug into the present era by modernizing the dosing regimen and advancing toward registration-directed trials with an aim of providing VAL-083 as a new therapeutic option for patients suffering from refractory GBM in the timeliest manner possible," Bacha added.

About the Planned Clinical Study

The Phase I/II study will 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®) and temozolomide (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).

The Company is planning to conduct the study under the direction of Dr. Howard Burris at the Sarah Cannon Research Institute in Nashville, Tennessee.

About Glioblastoma Multiforme (GBM)

Glioblastoma multiforme (GBM) is the most common and most malignant form of brain cancer. 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 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%. 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 the post-Avastin failure exceeds US$200 million annually in North America.

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 associated with alkylating events has been shown to differ from other alkylating agents used in the treatment of GBM.

VAL-083 has 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 methyltransferace (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 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 or contact
Jeffrey A. Bacha, President & CEO (604) 629-5989