September 8, 2015

DelMar Pharmaceuticals Presents Clinical Protocol for Advancement of VAL-083 into Phase IV Studies as a Treatment for Non-Small Cell Lung Cancer

- Growing body of recent data support VAL-083's potential as a treatment for drug-resistant non-small cell lung cancer -

VANCOUVER, British Columbia and MENLO PARK, Calif., Sept. 8, 2015 /PRNewswire/ -- DelMar Pharmaceuticals, Inc. (OTCQX: DMPI) ("DelMar" and the "Company"), a biopharmaceutical company focused on the development and commercialization of new cancer therapies, today presented an overview of its planned clinical trial protocol for Company's lead product candidate VAL-083 (*dianhydrogalactitol*) in the treatment of non-small cell lung cancer (NSCLC).

The Company presented the VAL-083 NSCLC clinical development plan in a poster entitled, *"Post-Market Clinical Trial of Dianhydrogalactitol in the Treatment of Relapsed or Refractory Non-Small Cell Lung Cancer"* at the 16th World Conference on Lung Cancer in Denver, Colorado.

VAL-083 is a "first-in-class" bi-functional alkylating agent meditating inter-strand DNA crosslinks at N^7 of guanine that has been approved by the Chinese Food and Drug Administration (CFDA) for the treatment of lung cancer. However, use of VAL-083 in China has been limited by a lack of modern data, poor distribution, and preference for targeted therapies such as tyrosine kinase inhibitors (TKIs) in the modern era.

The study will enroll up to 20 adult patients with NSCLC in an open-label post market Phase IV clinical trial to investigate the activity of VAL-083 in NSCLC patients who have failed standard platinum doublet therapy. The primary goal is the assessment disease control rate, defined as objective response rate, complete (CR) and partial (PR) response rates, and stable disease (SD). Secondary endpoints will include evaluation of progression free survival (PFS) and overall survival (OS). Results will provide guidance to treating physicians under the context of VAL-083's current approval in China and clinical proof-of-concept to support DelMar's global development of VAL-083 as a potential new treatment for NSCLC.

The clinical trial will be initiated in Shanghai under the terms of DelMar's collaboration with Guangxi Wuzhou Pharmaceutical (Group) Co., Ltd. Under the terms of the collaboration, Guangxi Wuzhou Pharmaceuticals is responsible for funding VAL-083 clinical research in China and DelMar is responsible for management of the clinical trials.

"Earlier this year, we presented preclinical data supporting the potential of VAL-083 as a valuable therapeutic option in the modern treatment of lung cancer, particularly in patients who have failed or are unlikely to respond to current standard of care. Our research also suggests that the combination of VAL-083 with either cisplatin or oxaliplatin provides a super-additive (synergistic) effect against NSCLC cell lines, including those resistant to TKI therapy in vitro," stated Jeffrey Bacha, president & CEO of DelMar Pharmaceuticals. "The upcoming Phase IV trial will further evaluate VAL-083's potential to address a significant unmet need in platinum drug-resistant NSCLC. The clinical outcomes from this study will be important in developing additional CFDA treatment guidelines to expand VAL-083 beyond its currently approved indication in lung cancer in China."

"Importantly, we believe data from this post-market study in China will also establish global proof-of-concept to support a global clinical development program with VAL-083 in NSCLC," Mr. Bacha added.

The trial will follow the dosing regimen in accordance with the approved label in China. Patients will receive VAL-083 intravenous (IV) dose of 40 mg/day for five consecutive days, with one to two weeks rest, for two courses, followed by maintenance therapy 40 mg/day IV for five consecutive days every 28 days. Patients will continue to receive treatment until withdrawal criteria are met or the patient receives up to 12 cycles of therapy, whichever comes first. Patients will be monitored for objective responses, progression-free survival, survival, and quality-of-life. Following tumor assessments at screening, evaluation of tumor response conforming to RECIST v1.1 will be documented prior to every other new 28-day maintenance treatment cycle, commencing with maintenance Cycle #2.

PHASE IV CLINICAL STUDY OF DIANHYDROGALACTITOL (VAL-083) IN RELAPSED OR REFRACTORY NSCLC

Protocol Summary

This is an open label post-market Phase IV study of VAL-083 in treatment of NSCLC patients who have failed standard platinum doublet therapy. Up to 20 patients will be enrolled into the study. Study patients will receive VAL-083 intravenous (IV) dose of 40 mg/day for five consecutive days, with 1-2 weeks rest, for two courses, followed by maintenance therapy 40 mg/day IV for five consecutive days every 28 days. Patients will continue to receive treatment until withdrawal criteria are met or the patient receives up to 12 cycles of therapy, whichever comes first. Patients will be monitored for objective responses, progression-free survival, survival, and quality-of-life (using a quality-of-life instrument for patients with lung cancer). Following tumor assessments at screening, evaluation of tumor response conforming to RECIST v1.1 will be documented prior to every other new 28-day maintenance treatment cycle, commencing with maintenance Cycle #2.

Primary goals

To determine activity of VAL-083 in NSCLC patients who have failed standard platinum doublet therapy, as assessed by disease control rate, defined as objective response rate, complete (CR) and partial (PR) response rates, and stable disease (SD) in order to provide guidance to treating physicians under the context of VAL-083's current approval in China.

Secondary goals

To determine the progression-free survival rate of NSCLC patients who have failed standard platinum doublet therapy when treated with VAL-083; to determine the overall survival of NSCLC patients who have failed standard platinum doublet therapy when treated with VAL-083; and to evaluate the quality of life and impact on disease symptoms following treatment with VAL-083.

Study duration
The study will be considered complete when the last patient either experiences disease progression or an intolerable toxicity, or withdraws from the study. The study is anticipated to take approximately 1-2 years.

The Company's poster presentation on the Phase IV post-market clinical protocol for VAL-083 in the treatment of relapsed or refractory non-small cell lung cancer may be found on DelMar's website under http://www.delmarpharma.com/products/publications/.

About Lung Cancer
Lung cancer is a leading cause of cancer-related mortality around the world. In general, prognosis for lung cancer patients remain poor, with 5-year relative survival less than 14% among males and less than 18% among females in most countries. Globally, the market for lung cancer treatments may exceed $7 billion by 2019 according to report published by Transparency Market research. Non-small cell lung cancer is the most common type of lung cancer, accounting for 85% of all lung cancer cases in the United States and approximately 90% of lung cancer cases diagnosed in China. NSCLC is usually treated with surgery followed by treatment with either tyrosine kinase inhibitors (TKIs) or platinum-based chemotherapy regimens. TKI resistance has emerged as a significant unmet medical need, and long-term prognosis with platinum-based therapies is poor.

About VAL-083
VAL-083 is a "first-in-class", small-molecule chemotherapeutic. In more than 40 Phase I and II clinical studies sponsored by the U.S. National Cancer Institute, VAL-083 demonstrated 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 (CML) and lung cancer and has received orphan drug designation in Europe and the U.S. for the treatment of gliomas.

DelMar is currently studying VAL-083 in a multi-center Phase I/II clinical trial for patients with refractory GBM in accordance with the protocol that has been filed with the U.S. Food and Drug Administration (FDA) at five clinical centers in the United States: Mayo Clinic (Rochester, MN); UCSF (San Francisco, CA) and three centers associated with the Sarah Cannon Cancer Research Institute (Nashville, TN, Sarasota, FL and Denver, CO). As a potential treatment for glioblastoma, VAL-083's mechanism of action appears to be unaffected by the expression of MGMT, a DNA repair enzyme that is implicated in chemotherapy resistance and poor outcomes following front-line treatment with Temodar® (temozolomide).

About DelMar Pharmaceuticals, Inc.
DelMar Pharmaceuticals, Inc. was founded to develop and commercialize proven cancer therapies in new orphan drug indications where patients are failing or have become intolerable to modern targeted or biologic treatments. The Company's lead drug in development, VAL-083, is currently undergoing clinical trials in the U.S. as a potential

treatment for refractory glioblastoma multiforme. VAL-083 has been extensively studied by U.S. National Cancer Institute, 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 that could provide improved treatment options for patients.

For further information, please visit http://delmarpharma.com/; or contact DelMar Pharmaceuticals Investor Relations: ir@delmarpharma.com / (604) 629-5989. Follow us on Twitter @DelMarPharma or Facebook.com/delmarpharma. Investor Relations Counsel: Amato & Partners LLC.

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.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/delmar-pharmaceuticals-presents-clinical-protocol-for-advancement-of-val-083-into-phase-iv-studies-as-a-treatment-for-non-small-cell-lung-cancer-300138648.html

SOURCE DelMar Pharmaceuticals, Inc.