

April 7, 2014



# DelMar Pharmaceuticals Presents Promising Pre-clinical Data with VAL-083 in Lung Cancer

**New data demonstrates VAL-083 is superior to standard platinum-based chemotherapy in an established in vivo model of non-small cell lung cancer (NSCLC)**

VANCOUVER, British Columbia, MENLO PARK, Calif. and SAN DIEGO, April 7, 2014 /PRNewswire/ -- [DelMar Pharmaceuticals, Inc.](#) (OTCQB: DMPI) ("DelMar") today announced the presentation of new data in a poster entitled, "*In vivo efficacy of VAL-083 in the treatment of non-small cell lung cancer.*" DelMar's data was presented on Sunday, April 6, 2014 during the Novel Cytotoxic Strategies Session at the 105th Annual Meeting of the American Association for Cancer Research (AACR) in San Diego.

VAL-083 is a structurally unique bi-functional alkylating agent approved for treatment of lung cancer in China and has documented activity against non-small cell lung cancer (NSCLC) in historical clinical trials sponsored by the United States National Cancer Institute.

The purpose of this pre-clinical study was to evaluate the activity of VAL-083 *in vivo* models of drug-resistant NSCLC in comparison to cisplatin.

In an established murine xenograft model of NSCLC, the activity of VAL-083 was compared to standard platinum-based therapy with cisplatin against human NSCLC cell lines A549 (TKI-sensitive) and H1975 (TKI-resistant). In the study, VAL-083 demonstrated superior efficacy and safety in the treatment of TKI-susceptible (A549) tumors and in TKI-resistant (H1975) tumors.

- Treatment of TKI-sensitive (A549) NSCLC with 3 mg/kg of VAL-083 resulted in tumor growth delay of 26 days compared to untreated controls. Cisplatin (5 mg/kg) resulted in tumor growth delay of just four days. In addition, mean tumor volume on day 68 was significantly reduced in animals treated with 3 mg/kg VAL-083 ( $p=0.001$ ) compared to untreated control.
- Treatment of TKI-resistant (H1975) NSCLC with 4 mg/kg of VAL-083 resulted in a statistically significant reduction in tumor volume ( $p = 0.01$ ) versus untreated control after 27 days. In the same model, treatment with 5 mg/kg of cisplatin failed to achieve statistically significant reduction in tumor volume ( $p = 0.23$ ) versus untreated control after 27 days. Longer-term safety assessments are ongoing in this model.

Jeffrey Bacha, president & CEO of DelMar said, "These data suggest that VAL-083 may be a viable treatment option for NSCLC patients failing TKI-therapy, especially where platinum-

based therapy has already failed or is predicted to give sub-optimal outcomes."

"These important results have immediate implications in the treatment of NSCLC in China, where VAL-083 is approved for as a chemotherapy for the treatment of lung cancer. The data also support exploring future clinical development of VAL-083 as a lung cancer therapy in the rest of the world thereby providing DelMar with a potential opportunity to expand our clinical development focus beyond glioblastoma."

The treatment of non-small cell lung cancer remains an unmet medical need. The median overall survival time for patients with stage IV non-small cell lung cancer (NSCLC) is four months, and one- and five-year survival is less than 16% and 2%, respectively.

Standard of care for NSCLC is surgery followed by treatment with either tyrosine kinase Inhibitors (TKIs) such as Tarceva® or platinum-based regimens. TKIs have resulted in vastly improved outcomes for many patients; however, TKI resistance has emerged as a significant unmet medical need, and long-term prognosis with platinum-based therapies remains poor. Additionally, the incidence of NSCLC spreading to the brain is high with very poor prognosis.

VAL-083 is currently undergoing a DelMar sponsored clinical trial in the United States as a potential new treatment for refractory glioblastoma. DelMar will present an update on this ongoing clinical trial during the Early Phase Clinical Trials 2 session on Wednesday, April 9, 2014, 8:00 am to 12:00 pm. A link to the abstract can be found here: [DMPI GBM AACR2014](#).

### **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 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 DelMar Pharmaceuticals**

DelMar Pharmaceuticals was founded in 2010 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 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 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 which distinct from current therapies.

## 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); or contact **Jeffrey A. Bacha, President & CEO (604) 629-5989** or **Booke & Company Investor Relations, [admin@bookeandco.com](mailto:admin@bookeandco.com)**.

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