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DelMar Pharmaceuticals Provides VAL-083 Updates from the Ongoing American Association for Cancer Research (AACR) Annual Meeting

VANCOUVER, British Columbia and MENLO PARK, Calif., April 5, 2017 /PRNewswire/ - DelMar Pharmaceuticals (Nasdaq: DMPI) ("DelMar" and the "Company"), a biopharmaceutical company focused on the development and commercialization of new cancer therapies, today announced that it has presented three abstracts at the American Association for Cancer Research (AACR) Annual Meeting. These abstracts are all focused on pre-clinical research to elucidate the mechanism of action (MOA) of DelMar Pharmaceuticals' lead anti-cancer product candidate, VAL-083 (dianhydrogalactitol), a "first-in-class" small-molecule, DNA-targeting, chemotherapeutic agent.

The AACR Annual Meeting is currently ongoing (April 1-5, 2017) in Washington, D.C.

Details of the poster presentations by DelMar and its collaborators from the MD Anderson Cancer Center and the University of British Columbia/BC Prostate Center are as follows:

Abstract #1429 - DNA damage response to dianhydrogalactitol (VAL-083) in p53-deficient non-small cell lung cancer (NSCLC) cells

Chemo-refractory NSCLC cells often demonstrate platinum resistance due to the presence of p53 mutations in these cells. Subsequently, such NSCLC tumors are also rendered resistant to tyrosine kinase inhibitors (TKIs) due to the accumulation of new mutations like T790M and KRAS. In this poster, the activity of VAL-083 is assessed in 11 different NSCLC cell lines. Using cytotoxicity assays (IC₅₀), VAL-083 was found to be active in all 11 cell lines irrespective of p53, KRAS and EGFR status. Furthermore, VAL-083 is active in cells with T790M and KRAS mutations indicating that this agent can overcome TKI-resistance. This poster demonstrates that VAL-083 has a differentiated MOA with a dual signaling pathway (p53 dependent and p53 independent signaling) to cause permanent DNA damage in NSCLC cell lines.

These preclinical results provide the scientific rationale for further assessment of VAL-083 in NSCLC in human clinical trials.

Abstract #2483 - [Molecular mechanisms of dianhydrogalactitol \(VAL-083\) in overcoming chemoresistance in glioblastoma](#)

Glioblastoma multiforme (GBM) is the most common but perhaps the most abysmal CNS tumor with a 5-year survival of ~3%. This poor prognosis is attributable to chemoresistance

to the current standard front-line chemotherapy—Temozolomide (TMZ). The activity of the enzyme O6-methyl guanine methyl transferase (MGMT) protects cancer cells against the activity of TMZ, rendering the GBM cells chemo-resistant to this front-line agent.

In this poster, the authors elucidate the unique MOA of VAL-083 which is a new small molecule, DNA-targeting agent that unlike TMZ is not inhibited by MGMT. By permanently damaging the tumor cell's DNA resulting in cell-cycle arrest in the G2/S phase, VAL-083 may have synergistic activity with S-phase specific drugs like topoisomerase inhibitors and PARP inhibitors.

Further, the authors support this theory by demonstrating the synergistic activity of VAL-083 with topoisomerase I/II inhibitors camptothecin and etoposide.

Abstract CT#054 - Phase II study of dianhydrogalactitol in patients with MGMT-unmethylated bevacizumab-naive recurrent glioblastoma

This abstract builds on the preclinical observations from Abstract#2483 which showed that compared to TMZ, the tumor cell DNA-damaging activity of VAL-083 is not lost in MGMT expressing GBM tumors. The authors also cite a previously completed VAL-083 Phase I/II study (ASCO 2016) where a meaningful overall survival (OS) of 8.35 months was demonstrated in 22, third-line GBM patients following failure of both TMZ and bevacizumab (Avastin®).

Given that VAL-083's activity is not lost even in MGMT-unmethylated GBM tumors, the authors provide a rationale to conduct a clinical trial of this novel agent as a second line therapy after TMZ failure, and not just as a third line therapy after TMZ and bevacizumab. The authors delineate the design of an ongoing, Phase 2, single arm, biomarker driven, MGMT unmethylated, clinical trial of VAL-083 in 48 GBM patients after their first recurrence, post radio-chemotherapy with TMZ.

Should the set efficacy benchmark be met in this trial, VAL-083 will be positioned to change the treatment paradigm in GBM by emphasizing biomarker testing for MGMT and the use of VAL-083 (perhaps even *in lieu* of TMZ) in all MGMT-unmethylated GBM patients.

The Company's presentations from the 2017 AACR Annual Meeting can be viewed via the [scientific-publications page on DelMar's website](#).

About VAL-083

VAL-083 is a "first-in-class," small-molecule DNA-targeting agent that demonstrated clinical activity against a range of cancers including GBM in historical clinical trials sponsored by the U.S. National Cancer Institute. DelMar has demonstrated that VAL-083's anti-tumor activity against GBM is unaffected by the expression of MGMT *in vitro*. Further details can be found at www.delmarpharma.com/scientific-publications.html.

VAL-083 has received an orphan drug designation in Europe for the treatment of malignant gliomas, and the U.S. FDA Office of Orphan Products has granted an orphan designation to VAL-083 for the treatment of glioma, medulloblastoma and ovarian cancer.

DelMar has also announced plans to advance VAL-083 into a pivotal randomized multi-

center Phase 3 clinical trial for the treatment of bevacizumab-failed GBM. A separate Phase 2 trial for MGMT-unmethylated recurrent GBM is currently open for enrollment at the University of Texas MD Anderson Cancer Center and an international trial for newly diagnosed MGMT-unmethylated GBM is expected to commence enrollment upon receipt of required government approval.

DelMar believes that data from its clinical trials, if successful, will form the basis of a new treatment paradigm for the vast majority of GBM patients whose tumors exhibit features that make them unlikely to respond to currently available therapies.

About DelMar Pharmaceuticals, Inc.

DelMar Pharmaceuticals, Inc. was founded to develop and commercialize new cancer therapies in indications where patients are failing or have become intolerable to modern targeted or biologic treatments. DelMar's VAL-083 is currently undergoing clinical trials in the U.S. as a potential new therapy for GBM. VAL-083 has been extensively studied by the U.S. National Cancer Institutes, and is currently approved for the treatment of chronic myelogenous leukemia 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. Connect with the Company on [Twitter](#), [LinkedIn](#), [Facebook](#), and [Google+](#).

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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-provides-val-083-updates-from-the-ongoing-american-association-for-cancer-research-aacr-annual-meeting-300434701.html>

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