DelMar Presents Poster of Clinical Research with VAL-083 in Patients with Chemo-resistant Glioblastoma ("GBM") at SNO's Pediatric Neuro-Oncology Basic and Translational Research Conference


The Company's presentation entitled "Dianhydrogalactitol (VAL-083) overcomes p53-mediated chemo-resistance and displays synergy with topoisomerase inhibitors" was presented the evening of Thursday, June 15.

The authors highlight the current absence of a viable standard-of-care for patients with pediatric high-grade gliomas (pHGG). This is because the only approved agent for this indication, temozolomide (TMZ), is rendered inactive due to pediatric brain tumors having a high expression of a TMZ-inactivating enzyme called MGMT* and a low expression of the TMZ-activating MMR** pathway proteins.

In prior clinical trials, DelMar Pharmaceuticals' lead product candidate VAL-083 demonstrated activity against this dire pediatric cancer. The poster emphasizes the fact that VAL-083 maintains functionality regardless of the MGMT or MMR status of pHGG, and is also not affected by the p53 status of the cancer cells. In vitro, VAL-083 has been shown to cause a robust and irreversible S/G2 arrest of the cancer cells, potentially then leading to cancer cell apoptosis. The poster provides the rationale for a detailed clinical investigation of VAL-083 in pediatric high-grade gliomas both as a single agent or in combination with currently available therapies such as TMZ or topoisomerase inhibitors.

*MGMT= 06-methylguanine-DNA methyltransferase  
**MMR= mismatch repair

"DelMar Pharmaceuticals is excited to share the promising horizon that VAL-083 results have shown in the treatment of pediatric brain tumor," said Jeffrey Bacha, chairman & CEO of DelMar. "We are conscious of the difference VAL-083 could make in the lives of
patients and their families, and we are driven by the determination of improving patient outcomes. We are confident that our research efforts will make an impactful contribution to the community and this area of science."

About VAL-083

Dianhydrogalactitol (VAL-083) is a "first-in-class", DNA-targeting agent that introduces interstrand DNA cross-links at the N7-position of guanine leading to DNA double-strand breaks and cancer cell death. VAL-083 has demonstrated clinical activity against a range of cancers including GBM in historical clinical trials sponsored by the U.S. National Cancer Institutes.

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

DelMar has demonstrated that VAL-083's anti-tumor activity against GBM is unaffected by the expression of MGMT \textit{in vitro}. Further details regarding these studies can be found at \url{http://www.delmarpharma.com/scientific-publications.html}.

DelMar's recent outcomes in Phase 1-2 clinical trials suggested that VAL-083 may offer a clinically meaningful survival benefit for patients with recurrent GBM following treatment with both TMZ and bevacizumab. A well-tolerated dosing regimen of 40mg/m$^2$/day on days 1, 2, and 3 of a 21-day cycle was selected for study in subsequent GBM clinical trials.

DelMar has embarked human clinical trials for VAL-083 across every line of GBM therapy. These trials include, i) an ongoing single-arm, biomarker driven, Phase 2 study to determine if VAL-083 treatment of MGMT-unmethylated adult GBM patients at first recurrence/progression, prior to bevacizumab improves overall survival, compared to historical control with lomustine (\url{clinicaltrials.gov identifier: NCT02717962}). ii) A pivotal, controlled Phase 3 study in temozolomide-Avastin Recurrent GBM ("STAR-3") to evaluate overall survival versus salvage chemotherapy (\url{clinicaltrials.gov identifier: NCT03149575}). iii) A single arm, biomarker driven, Phase 2 study to confirm the tolerability and efficacy of VAL-083 in combination with radiotherapy in newly diagnosed MGMT-unmethylated GBM patients whose tumors are known to express high MGMT levels. (\url{clinicaltrials.gov identifier: NCT03050736}). The results of these studies may support a new treatment paradigm in chemotherapeutic regimens for the treatment of GBM.

About Glioblastoma Multiforme (GBM)

Glioblastoma (GBM) is the most common and aggressive primary brain cancer. Current standard of care includes surgery, radiation and treatment with temozolomide (TMZ), however nearly all tumors recur and the prognosis for recurrent GBM is dismal. Most GBM tumors have unmethylated promoter status for O6-methylguanine-DNA-methyltransferase (MGMT); a validated biomarker for TMZ-resistance. Second-line treatment with anti-angiogenic agent bevacizumab has not improved overall survival (OS) and 5-year survival is less than 3%.
About DelMar Pharmaceuticals, Inc.

DelMar Pharmaceuticals, Inc. was founded in 2010, driven by the passion of its initiators to develop and commercialize unique new cancer therapies that save and improve lives in indications where patients are failing or have become intolerable to modern targeted or biologic treatments. DelMar’s lead product candidate 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 Institute, 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.

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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.


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