

## DelMar Provides Clinical Update on VAL-083 from Ongoing First- and Second-Line Trials in Patients with MGMT-unmethylated Glioblastoma at a Key Opinion Leader Forum during the American Society of Clinical Oncology (ASCO) Annual Meeting

VANCOUVER, British Columbia and MENLO PARK, Calif., June 3, 2019 /PRNewswire/ --[DelMar Pharmaceuticals, Inc.](#) (NASDAQ: DMPI) ("DelMar" or the "Company"), a biopharmaceutical company focused on the development of novel cancer therapies presented clinical updates from the Company's ongoing first- and second-line trials in patients with MGMT-unmethylated glioblastoma multiforme (GBM) at a key opinion leader (KOL) forum focused on brain tumors and the role of VAL-083 to address the unmet medical need in GBM during the 2019 American Society of Clinical Oncology (ASCO) annual meeting in Chicago, IL.

At the KOL forum, the Company provided an update on the ongoing Phase 1/2 clinical study investigating the front line treatment of VAL-083 with radiation therapy in newly diagnosed MGMT-unmethylated GBM. This trial is being conducted at the Sun Yat-sen University Cancer Center (SYSUCC) in Guangzhou, China in collaboration with Guangxi Wuzhou Pharmaceutical Company. The trial is designed to enroll up to 30 patients to determine if first-line therapy with VAL-083 treatment, in lieu of first-line temozolomide, improves progression free survival (PFS).

As of May 17, 2019, eighteen patients have been enrolled in the trial. Of these patients, fifteen have received their post-cycle 3 MRI and investigator assessment, and ten have received their post-cycle 7 MRI and investigator assessment. Two patients have not been on the study long enough to reach their first assessment, and one patient died before their first assessment. Assessments are based on the trial investigator's clinical and radiologic assessment, according to the Response Assessment in NeuroOncology (RANO) criteria. For the fifteen patients who have received at least one assessment, eight patients were assessed with a best response of "Complete Response" (8/15, 53.3% CR) and seven patients were assessed with a best response of "Stable Disease" (7/15, 46.7% SD). Fourteen of the eighteen patients were still alive at the data cut-off date.

The Company also provided an update on the ongoing second-line Phase 2 clinical study of VAL-083 in patients with MGMT-unmethylated, Bevacizumab-naïve recurrent GBM. This study is being conducted in collaboration with The University of Texas MD Anderson Cancer Center (MDACC). This biomarker-driven trial (testing for MGMT methylation status) has been amended to enroll up to 83 patients (35 with a starting dose of 40 mg/m<sup>2</sup>; 48 with a starting dose of 30 mg/m<sup>2</sup>) to determine the potential of VAL-083 treatment to improve overall survival compared to historical reference control of 7.2 months with lomustine.

- As of May 5, 2019, 51 patients have been enrolled, 35 patients at a starting dose of 40 mg/m<sup>2</sup>, and 16 patients at a starting dose of 30 mg/m<sup>2</sup>.
- For the 47 patients who have been on study long enough to be assessed at the post-cycle 2 MRI:
  - 9/35 (25.7%) patients initially receiving 40 mg/m<sup>2</sup> exhibited "Stable Disease" per investigator assessment at the end of cycle 2
  - 4/12 (33.3%) patients initially receiving 30 mg/m<sup>2</sup> exhibited "Stable Disease" per investigator assessment at the end of cycle 2

Additionally, the study protocol has been amended to include enrollment of up to 24 newly-diagnosed GBM patients who have completed chemoradiation treatment with TMZ and received no subsequent TMZ maintenance therapy but will receive VAL-083 instead (Group 2). This Group has been included to explore whether earlier intervention with VAL-083 instead of TMZ maintenance therapy offers clinical benefit and extends the time to recurrence as compared to TMZ maintenance therapy.

Consistent with prior studies, myelosuppression (primarily thrombocytopenia and neutropenia) is the most common adverse event in both ongoing clinical trials.

"We are pleased with the progress to date with our two Phase 2 programs for VAL-083. In our view, these results support the preclinical and prior clinical efficacy that was observed in the MGMT-unmethylated GBM population. Additionally, we continue to view the 2017 revised NCCN guidelines for MGMT-unmethylated GBM patients quite favorably for VAL-083, which cautions against the use of temozolomide (TMZ) for this particular patient population. The MGMT-unmethylated patients represent over 60% of the GBM cases and the revised NCCN guidelines expand the therapeutic opportunity for VAL-083 to all major lines of GBM treatment from front-line and maintenance as well as second line (recurrent) GBM," commented Saiid Zarrabian, DelMar's Chief Executive Officer.

### **About VAL-083**

VAL-083 (dianhydrogalactitol) is a "first-in-class", bifunctional DNA-targeting agent that introduces inter-strand 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 and ovarian cancer in historical clinical trials sponsored by the U.S. National Cancer Institute (NCI). DelMar has demonstrated that VAL-083's anti-tumor activity is unaffected by common mechanisms of chemoresistance, including MGMT, in cancer cell models and animal studies. Further details regarding these studies can be found at:

<http://www.delmarpharma.com/scientific-publications.html>.

VAL-083 has been granted orphan drug designations 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. VAL-083 has been granted fast-track status for the treatment of recurrent GBM by the US FDA.

### **About DelMar Pharmaceuticals, Inc.**

DelMar is focused on the development and commercialization of new therapies for cancer patients who have limited or no treatment options. By focusing on understanding tumor biology and mechanisms of treatment resistance, the Company identifies biomarkers to personalize new therapies in indications where patients are failing, or are unable to tolerate, standard-of-care treatments.

The Company's current pipeline is based around VAL-083, a "first-in-class", small-molecule chemotherapeutic with a novel mechanism of action that has demonstrated clinical activity against a range of cancers including central nervous system, ovarian and other solid tumors (e.g. NSCLC, bladder cancer, head & neck) in U.S. clinical trials sponsored by the NCI. Based on DelMar's internal research programs, and these prior NCI-sponsored clinical studies, the Company is conducting clinical trials to support the development and commercialization of VAL-083 to solve significant unmet medical needs.

VAL-083 is being studied in two collaborator-supported, biomarker-driven, Phase 2 clinical trials for MGMT-unmethylated GBM. Overcoming MGMT-mediated resistance represents a significant unmet medical need in the treatment of GBM. In addition, DelMar has announced the allowance of a separate IND for VAL-083 as a potential treatment for platinum-resistant ovarian cancer.

Further information on DelMar's clinical trials can be found on [clinicaltrials.gov](http://clinicaltrials.gov):

<https://www.clinicaltrials.gov/ct2/results?cond=&term=val-083&cntry1=&state1=&recrs>

For additional information, please visit <http://delmarpharma.com/>; or contact DelMar Pharmaceuticals Investor Relations: [ir@delmarpharma.com](mailto:ir@delmarpharma.com) / (604) 629-5989.

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### **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 the Company's filings with the SEC, including, the Company's Annual Report on Form 10-K for the year ended June 30, 2018, the Company's Quarterly Reports on Form 10-Q, and the

Company's Current Reports on Form 8-K.



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