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DelMar Pharmaceuticals Presents Positive Interim Data of VAL-083 Demonstrating Favorable Outcomes In Both Recurrent and Newly-Diagnosed GBM

In the news release, DelMar Pharmaceuticals Presents Positive Interim Data of VAL-083 Demonstrating Favorable Outcomes In Both Recurrent and Newly-Diagnosed GBM, issued 25-Nov-2019 by DelMar Pharmaceuticals, Inc. over PR Newswire, we are advised by the company that the eighth paragraph, third and fourth sentences, contains updates to the percentage of improvement in PFS and mOS. The complete, corrected release follows:

DelMar Pharmaceuticals Presents Positive Interim Data of VAL-083 Demonstrating Favorable Outcomes In Both Recurrent and Newly-Diagnosed GBM

Newly-Diagnosed Patients Showing Promising Progression-Free Survival Compared to TMZ Historical Data

Recurrent Patients Showing Promising Overall Survival Compared to Lomustine Historical Data

SAN DIEGO, Nov. 25, 2019 /PRNewswire/ --[DelMar Pharmaceuticals, Inc.](#) (Nasdaq: DMPI) ("DelMar" or the "Company"), a biopharmaceutical company focused on the development of new solid tumor cancer therapies, today announced interim data on its two Phase 2 trials of VAL-083, the Company's lead compound for the treatment of glioblastoma multiforme (GBM). The data were presented in two posters at the 2019 Society for NeuroOncology Annual Meeting in Phoenix, Ariz.

First-Line GBM

The first poster outlined the open-label, Phase 2 study of VAL-083 as a first-line treatment in newly-diagnosed, unmethylated GBM patients. This study has enrolled 23 out of a planned 30 patients as of the data cut-off date of November 2, 2019. For the 22 patients who had completed at least one cycle of treatment as of that date, median progression-free survival (PFS) with VAL-083 is currently 9.9 months (confidence interval, or CI 7.3-12.0 months). For the 18 patients initially receiving the intended treatment dose (30 mg/m²/day on days 1, 2 and 3 of a 21-day cycle) median PFS is currently 10.4 months (CI 6.0-12.0 months). While this is not a head-to-head trial, historically, temozolomide (TMZ) has been demonstrated to have 6.9 months PFS in unmethylated GBM patients. Other doses were also examined as

part of the dose escalation aspect of the study, and all but the 20 mg/m²/day dose also demonstrated superior PFS to the historical comparator. A median of eight cycles of treatment has been received by all patients who had either completed treatment or remain in active treatment. Nine patients have received more than 10 cycles. This study is being conducted at Sun Yat-sen University Cancer Center in China.

Recurrent GBM

The second poster outlined interim data from two groups of patients receiving VAL-083 in the open-label, Phase 2 study in recurrent and adjuvant unmethylated GBM settings. The recurrent group is receiving second-line therapy with VAL-083 following TMZ failure. Sixty-two patients (out of a planned 83) have been enrolled as of the data cut-off of November 15, 2019, with 35 patients having received an initial dose of 40 mg/m²/day and 27 (out of a planned 48) having received an initial dose of 30 mg/m²/day (on days 1, 2 and 3 of a 21-day cycle). Median overall survival (mOS) for the 60 patients who have completed at least one cycle of treatment is currently 7.5 months (CI 6.0-11.5 months). For the 25 of those patients who initially received the intended treatment dose of 30 mg/m²/day, mOS is currently 10.6 months (CI 5.8-10.6 months). While this is not a head-to-head trial, historically lomustine, which is the most commonly used chemotherapy for these patients, has demonstrated a mOS of 7.2 months.

The second arm of this study, in which patients receive VAL-083 as adjuvant therapy following treatment with radiation and TMZ, was initiated in July 2019. As of the data cut-off of November 15, 2019, five patients (out of a planned 20) have been enrolled and all patients remain alive on continued therapy. The study in recurrent and adjuvant GBM is being conducted at M.D. Anderson Cancer Center in Houston, Tex.

Similar to prior experience with VAL-083, myelosuppression has been the most common adverse event observed. Four subjects have experienced a serious adverse event (SAE) possibly related to VAL-083 in the newly-diagnosed group, eleven subjects have experienced a possibly drug-related SAE in the recurrent group, and no patients have experienced a possibly drug-related SAE in the adjuvant group as of the relevant data cut-off dates.

During a review of the data, which was conducted at the SNO conference, Dr. David Reardon, clinical director of the Center for Neuro-Oncology at the Dana-Farber Cancer Institute, Professor of Medicine at the Harvard Medical School and member of DelMar's Scientific Advisory Board stated, "Putting it into the perspective of what has benefitted our patients historically, which has been a cytotoxic treatment approach like Delmar's VAL-083, we have had other classes of anticancer therapies that have unfortunately been quite disappointing. So, with VAL-083 we have a mechanism of action that has a proven track record and a rationale for why it may be superior to what we have currently. All of those factors explain why it has been challenging to move the bar in this disease. That said, I think there is some reason to be hopeful that this has a likelihood of further confirming the signals we have seen so far."

Dr. Nick Butowski, director of translational research in neuro-oncology and a researcher at the Brain Tumor Center and also a member of DelMar's Scientific Advisory Board added, "Upon reviewing the analysis from both studies, mechanistically, survival data-wise,

imaging-wise, quality of life and safety data are all very intriguing and exciting. Obviously, we need to see the completed data and then move on to the next steps."

Saïd Zarrabian, CEO of DelMar Pharmaceuticals stated: "We continue to be encouraged with the interim outcomes for both of our ongoing Phase 2 trials of VAL-083 in GBM. Our first-line treatment study continues to show outstanding results and we are particularly pleased to see VAL-083 at the 30 mg dose currently showing a full three months longer progression-free survival. This represents a PFS improvement of around 50% over temozolomide, the current standard of care. We are also encouraged by the 30 mg dose in the recurrent patient cohort, currently showing an improvement to median overall survival of more than three months, or approximately 47%, over historical published results from the current standard of care. We look forward to providing subsequent updates in 2020 at the American Association for Cancer Research and American Society of Clinical Oncology conferences."

The Company's current cash resources are expected to be sufficient to fund the Company's planned operations into the fourth quarter of calendar year 2020, and to allow for funding to top-line results for our newly-diagnosed and recurrent setting studies, and for full enrollment for the adjuvant study arm patients.

ABOUT DELMAR PHARMACEUTICALS

Located in San Diego, California, 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 National Cancer Institute (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.

Further information on DelMar's clinical trials can be found on [clinicaltrials.gov](https://www.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 / (604) 629-5989.

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, including statements regarding the status of the Company's clinical trials and the reporting of the results. 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, 2019, the Company's Quarterly Reports on Form 10-Q, and the Company's Current Reports on Form 8-K.

CONTACTS:

Investors:

John Marco
Managing Director
CORE IR
516-222-2560
johnm@coreir.com

Media:

Jules Abraham
Director of Public Relations
CORE IR
917-885-7378
julesa@coreir.com



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