

DelMar Pharmaceuticals Presents Positive Interim Data on VAL-083 Demonstrating Favorable Outcomes in Both Newly- Diagnosed and Recurrent GBM at the AACR Virtual Annual Meeting II

Findings Support Commencement of VAL-083's Participation in Pivotal GCAR GBM AGILE Study



NEWS PROVIDED BY

DelMar Pharmaceuticals, Inc. →

Jun 22, 2020, 08:30 ET

SAN DIEGO, June 22, 2020 /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 positive interim data from its two Phase 2 trials of VAL-083 for the treatment of glioblastoma multiforme (GBM) demonstrating improved outcomes over current standard of care as both a first-line treatment and for recurrent GBM. The data, presented in two posters at the 2020 American Association for Cancer Research Virtual Annual Meeting II, support the Company's planned participation in the Global Coalition for Adaptive Research's (GCAR) Glioblastoma Adaptive Global

Innovative Learning Environment (GBM AGILE) clinical trial. DelMar previously announced its invitation from GCAR to participate in the selective GBM AGILE study. This pivotal study, with its robust trial design, industry leading partners, and strong regulatory endorsement, is intended to serve as the basis for VAL-083's new drug application (NDA) submission and registration.

Dr. John de Groot, Chairman of the Department of Oncology at MD Anderson Cancer Center and planned Principal Investigator for the VAL-083 arm of the GCAR GBM AGILE registration study, noted, "These data continue to demonstrate an improvement over the historical outcomes of standard therapy and validate VAL-083's inclusion in a more robust setting as part of the GBM AGILE study. In MD Anderson's Glioblastoma Moon Shots Program, we are looking to create giant leaps to help patients with GBM where treatment options are limited. It is our hope that VAL-083 may serve as an important new therapy to help physicians and patients dramatically reduce mortality and suffering due to this deadly cancer. We continue to be encouraged by these results and are excited by the opportunity to collaborate with DelMar and GCAR to further explore the potential of VAL-083."

Interim outcomes included:

Poster #CT273 - "Phase 2 study of dianhydrogalactitol (VAL-083) in patients with newly diagnosed MGMT-unmethylated glioblastoma"

Results:

- For the 25 patients initially receiving the treatment dose that will be carried forward in the GBM AGILE pivotal study (30 mg/m²/day on days 1, 2 and 3 of a 21-day cycle) median progression-free survival (PFS) was reported to be 8.7 months (confidence interval, or CI 6.0-12.0 months) as of the May 15, 2020 cut-off date.
- Overall PFS (n=29) with VAL-083 was 8.7 months (CI 6.4-11.2 months).
- While not a head-to-head trial, historically temozolomide (TMZ), the standard of care, has been demonstrated to have 6.9 months PFS in newly diagnosed unmethylated GBM patients.

The open-label Phase 2 study in newly-diagnosed unmethylated GBM is being conducted at Sun Yat-sen University Cancer Center in China. The Company announced full enrollment of the study on February 19, 2020.

Poster #CT272 - "Phase 2 study of dianhydrogalactitol (VAL-083) in patients with MGMT-unmethylated bevacizumab-naïve glioblastoma in the recurrent of adjuvant setting"

Results:

- In recurrent GBM, for the 37 patients initially receiving the intended treatment dose that will be carried forward in the GBM AGILE pivotal study (30 mg/m²/day on days 1, 2 and 3 of a 21-day cycle), median overall survival (mOS) is currently 8.5 months (CI 5.7-14.3 months) as of the May 28, 2020 cut-off date.
- Overall mOS for the 72 patients who have completed at least one cycle of treatment was 7.1 months (CI 5.8-9.9 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 in recurrent unmethylated GBM patients.
- In the adjuvant setting, patients receive VAL-083 as adjuvant therapy following treatment with radiation and TMZ. As of the data cut-off date of May 28, 2020, 19 evaluable subjects have completed at least one 21-day cycle of treatment, with a total of 25 subjects enrolled. Enrollment for this arm was initiated in July 2019, and all 25 subjects enrolled to-date were alive at the data cut-off date.
- Based on encouraging outcomes, the Company plans to increase the adjuvant arm from the originally planned 24 patients to include up to 12 additional patients.

The open-label Phase 2 study in recurrent and adjuvant unmethylated GBM is being conducted at M.D. Anderson Cancer Center in Houston.

Dr. Barbara O'Brien, Principal Investigator, commented, "These results continue to demonstrate the promise of VAL-083, along with a very favorable safety profile in both the adjuvant and recurrent settings. Further, we are excited to be able to add additional patients to the adjuvant arm of the study, which has received great interest from patients, and has enrolled faster than predicted. VAL-083 is well tolerated by these patients and extending the study provides an opportunity for patients to have access to this important trial for glioblastoma."

Similar to prior experience with VAL-083, myelosuppression has been the most common adverse event observed. Three subjects experienced a serious adverse event (SAE), possibly related to VAL-083 in the newly-diagnosed group, while 10 subjects have experienced a possibly drug-related SAE in the recurrent group, and one patient has experienced a possibly drug-related SAE in the adjuvant group as of the relevant data cut-off dates.

Saiid Zarrabian, CEO of DelMar Pharmaceuticals, added, "We continue to be encouraged with the interim outcomes for both of our ongoing Phase 2 trials of VAL-083 in GBM. With the support of these findings, we have commenced preparations for VAL-083's participation in the GCAR pivotal GBM AGILE study. We look forward to reporting top-line results for the newly diagnosed Phase 2 study in the third quarter of 2020 and providing additional updates on both studies at the Society for Neuro-Oncology Annual Scientific Meeting in November 2020."

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, DelMar identifies biomarkers to personalize new therapies in indications where patients are failing, or are unable to tolerate, standard-of-care treatments.

DelMar'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 and 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, DelMar 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](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 GBM AGILE study, the status of the Company's clinical trials, the reporting of the results and the impact of the COVID-19 pandemic. 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 impact of the COVID-19 pandemic on the Company's operations and clinical trials, 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

SOURCE DelMar Pharmaceuticals, Inc.

Related Links

<http://delmarpharma.com>

