

June 4, 2020



# **Global Coalition for Adaptive Research (GCAR) Selects DelMar Pharmaceuticals' VAL-083 to Participate in the GBM AGILE Pivotal Study, an Adaptive Clinical Trial Platform in Glioblastoma Multiforme**

**GBM AGILE is the world's first global adaptive clinical trial platform for glioblastoma with regulatory support as a registrational study**

**VAL-083 selected as the next investigational therapy to be evaluated across multiple international trial sites**

**Reduces time for VAL-083's pivotal trial completion and regulatory submission by up to 18 months**

SAN DIEGO, June 4, 2020 /PRNewswire/ -- [DelMar Pharmaceuticals, Inc.](#) (Nasdaq: DMPI) ("DelMar" or the "Company"), a biopharmaceutical company focused on the development of new solid tumor cancer therapies, announced today the acceptance of an invitation from the Global Coalition for Adaptive Research (GCAR) to include VAL-083 in GCAR's Glioblastoma Adaptive Global Innovative Learning Environment (GBM AGILE) Study, an adaptive clinical trial platform in glioblastoma multiforme (GBM). DelMar will utilize the GBM AGILE study to serve as the basis for VAL-083's new drug application (NDA) submission and registration.

"We wish to convey our gratitude to GCAR for extending an invitation to DelMar to participate in the GBM AGILE study. We believe that GCAR's already-approved robust adaptive trial design, industry leading partners and clinical support vendors, as well as strong regulatory endorsement can measurably accelerate our efforts to bring VAL-083 to market for GBM patients who have significant unmet medical needs," commented Saiid Zarrabian, Chief Executive Officer of DelMar Pharmaceuticals. "With 24 clinical sites currently enrolling patients and with additional sites in the US, Canada, Europe and China expected to come online in the next 12 months, our participation in GBM AGILE is expected to provide a significant time and cost savings advantage related to clinical trial initiation. We look forward to enrolling the first patient into the VAL-083 arm of the study which is planned for the fourth quarter of this year."

GBM AGILE is an international effort in newly-diagnosed and recurrent GBM, utilizing an FDA approved master protocol with multiple drugs to be tested simultaneously and over time against a common control arm. As an approved registrational study, results from the

VAL-083 arm of GBM AGILE are intended to be utilized to file for FDA approval. This study employs a cost-efficient, adaptive trial design with a Stage 1 (Phase 2) learning and adapting phase and a Stage 2 (Phase 3) expansion and confirmation phase. The effort is led by top-tier key opinion leaders in the GBM field and has the collective support of an international group of more than 130 clinicians, researchers, biostatisticians, imagers, pathologists, leaders from government and industry, and patient advocates. GCAR is a 501(c)(3) organization that functions as GBM AGILE study sponsor, and provides financial support for the program infrastructure, as well as general trial oversight. Comprising the world's foremost clinical, translational, and basic science investigators, GCAR strives to support the development of novel treatments to fight against rare and deadly diseases like GBM where patient prognosis is poor and treatment options are limited.

"We look forward to advancing DelMar's promising compound, VAL-083, in GBM AGILE. This registrational study is designed to accelerate the identification and approval of new drugs for patients with glioblastoma, a challenging disease with limited treatment options. We are very pleased to collaborate with DelMar Pharmaceuticals to initiate planning for the inclusion of VAL-083 in the trial for recurrent and newly-diagnosed GBM patients," commented Meredith Buxton, PhD, MPH, Chief Executive Officer of GCAR.

## **ABOUT GLOBAL COALITION FOR ADAPTIVE RESEARCH**

GCAR is a 501(c)(3) nonprofit organization, comprised of some of the world's foremost physicians, clinical researchers and investigators united in expediting the discovery and development of cures for patients with rare and deadly diseases. As its first priority, GCAR is sponsoring GBM AGILE, an adaptive platform trial for patients with GBM – the most common and deadliest of malignant primary brain tumors. Key strategic partners for the GBM AGILE study effort include the National Brain Tumor Society, National Foundation for Cancer Research, and Asian Fund for Cancer Research. These three nonprofit organizations are working together to provide philanthropic support as well as assistance in communicating with patients and families and inviting all others to join in supporting this innovative approach to brain tumor treatment development.

## **ABOUT DELMAR PHARMACEUTICALS, INC.**

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. 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](mailto: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 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.

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