May 11, 2017

DelMar Formalizes Collaboration with PRA Health Sciences for Phase 3 Trial of VAL-083 in Recurrent Glioblastoma Multiforme (GBM)

VANCOUVER, British Columbia and MENLO PARK, Calif., May 11, 2017 /PRNewswire/ -- DelMar Pharmaceuticals (Nasdaq: DMPI) ("DelMar" and the "Company"), a biopharmaceutical company focused on developing new cancer therapies, today announced the formalization of an agreement with PRA Health Sciences (Nasdaq: PRAH), a leading contract research organization (CRO) to conduct the Company's Phase 3 trial of VAL-083 in recurrent glioblastoma multiforme (GBM).

"We have been working with PRA for quite some time in preparing for VAL-083's Phase 3 study in GBM," said Jeffrey Bacha, chairman and chief executive officer of DelMar Pharmaceuticals. "Given our recent $9M financing, we have the resources to facilitate the initiation of our pivotal Phase 3 study of VAL-083 as a single agent treatment for GBM patients who have failed both temozolomide (Temodar™) and bevacizumab (Avastin™), for whom there is no currently approved therapy. We are delighted to formally engage with a CRO of the caliber and reputation of PRA to run this Phase 3 study of a treatment for a cancer indication in which there is an utmost medical need in the eyes of oncologists and the FDA."

PRA Health Sciences is one of the world's leading global contract research organizations by revenue, providing outsourced clinical development services to the biotechnology and pharmaceutical industries. PRA's global clinical development platform includes more than 70 offices across North America, Europe, Asia, Latin America, South Africa, Australia and the Middle East, and approximately 13,000 employees worldwide. Since 2000, PRA has performed approximately 3,500 clinical trials worldwide and has worked on more than 100 marketed drugs across several therapeutic areas. In addition, PRA has participated in the pivotal or supportive trials that led to U.S. Food and Drug Administration or international regulatory approval of more than 70 drugs.

About VAL-083

VAL-083 is a "first-in-class," small-molecule chemotherapeutic that demonstrated clinical activity against a range of cancers including GBM in historical clinical trials sponsored by the U.S. National Cancer Institutes (NCI). DelMar has demonstrated that VAL-083's anti-tumor activity against GBM is unaffected by the expression of MGMT and MMR *in vitro.* Further details can be found at http://www.delmarpharma.com/scientific-publications.html.

VAL-083 has received an orphan drug designation in Europe for the treatment of malignant

gliomas and the U.S. FDA Office of Orphan Products has granted an orphan designation to VAL-083 for the treatment of glioma, medulloblastoma and ovarian cancer. Based on historic clinical trials run by the NCI, the modern Phase 1/2 dose finding trial run by DelMar in GBM (ASCO 2016), and recent guidance from the FDA, the Company has embarked on Phase 2 or 3 trials for VAL-083 across recurrent and newly diagnosed GBM. DelMar has announced plans to advance VAL-083 into a controlled Phase 3 **S**tudy in **T**emozolomide-**A**vastin **R**ecurrent GBM *(**"STAR-3"**)* to evaluate overall survival versus salvage chemotherapy for GBM patients who have previously failed both temozolomide and bevacizumab (Avastin™) and for whom there exists no approved treatment option; a Phase 2 trial (with MD Anderson Cancer Center) in first recurrence GBM patients prior to bevacizumab therapy is currently enrolling; and a separate international Phase 2 trial for newly diagnosed MGMT-unmethylated GBM is planned. DelMar believes that data from its clinical trials, if successful, will form the basis of a new treatment paradigm for the vast majority of GBM patients whose tumors exhibit features that make them unlikely to respond to currently available therapies.

About Glioblastoma Multiforme (GBM)

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 MGMT. Second-line treatment with anti-angiogenic agent bevacizumab has not improved overall survival (OS) and 5-year survival is less than 3%. VAL-083 (*dianhydrogalactitol*) is a first-in-class bi-functional DNA-targeting agent that induces interstrand DNA cross-links at the N7-position of guanine leading to DNA double-strand breaks and cell death in GBM cell lines and GBM cancer stem cells, independent of MGMT or MMR status *in vitro*. VAL-083 readily crosses the blood-brain barrier and accumulates in brain tumor tissue. Our recent Phase 1/2 clinical trial in recurrent GBM patients failing both TMZ and bevacizumab, suggested that VAL-083 offers clinically meaningful survival benefits for patients with recurrent GBM and pinpointed a new dosing regimen (40 mg/m^2/d on days 1,2,3 of a 21-day cycle) which was well-tolerated and was selected for study in subsequent GBM trials. 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 (clinicaltrials.gov identifier: NCT02717962) ii) A pivotal controlled Phase 3 **S**tudy in **T**emozolomide-**A**vastin **R**ecurrent GBM *(**"STAR-3"**)* to evaluate the overall survival of VAL-083 versus salvage chemotherapy for GBM patients who have previously failed both temozolomide and bevacizumab (Avastin™).The control arm will consist of a limited number of salvage chemotherapies currently used in bevacizumab-failed GBM. If successful, this study will serve as the basis for a New Drug Application (NDA) submission for VAL-083. 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. The results of these studies may support a new treatment paradigm in chemotherapeutic regimens for the treatment of GBM.

About DelMar Pharmaceuticals, Inc.

DelMar Pharmaceuticals, Inc. was founded to develop and commercialize new cancer therapies in indications where patients are failing or have become intolerable to modern

targeted or biologic treatments. DelMar's 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 Institutes, 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.

For further information, please visit http://delmarpharma.com/; or contact DelMar Pharmaceuticals Investor Relations: ir@delmarpharma.com / (604) 629-5989. Connect with the Company on Twitter, LinkedIn, Facebook, and Google+.

About PRA Health Sciences

PRA is one of the world's leading global contract research organizations, by revenue, providing outsourced clinical development services to the biotechnology and pharmaceutical industries. PRA's global clinical development platform includes more than 70 offices across North America, Europe, Asia, Latin America, South Africa, Australia and the Middle East, and approximately 13,000 employees worldwide. Since 2000, PRA has performed approximately 3,500 clinical trials worldwide and has worked on more than 100 marketed drugs across several therapeutic areas. In addition, PRA has participated in the pivotal or supportive trials that led to U.S. Food and Drug Administration or international regulatory approval of more than 70 drugs. To learn more about PRA, please visit www.prahs.com.

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 our filings with the SEC, including, our current reports on Form 8-K.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/delmar-formalizes-collaboration-with-pra-health-sciences-for-phase-3-trial-of-val-083-in-recurrent-glioblastoma-multiforme-gbm-300455809.html

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