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DelMar Pharmaceuticals Presents Promising Preclinical Data on VAL-083's Potential to Treat Temozolomide-Resistant Glioblastoma Multiforme (GBM)

- Data supports potential to address a significant unmet need as a therapeutic option for temozolomide-resistant GBM -

VANCOUVER, British Columbia and MENLO PARK, Calif., April 20, 2015 /PRNewswire/ -- DelMar Pharmaceuticals, Inc. (OTCQX: DMPI) (DelMar and the Company), a biopharmaceutical company focused on developing and commercializing proven cancer therapies in new orphan drug indications, today announced promising preclinical data at the 106th Annual Meeting of the American Association for Cancer Research (AACR) Annual Meeting on the potential for its lead product candidate VAL-083 (dianhydrogalactitol) to treat patients with temozolomide-resistant glioblastoma multiforme (GBM).

The objective of the VAL-083 study entitled, *"Dianhydrogalactitol inhibits the growth of glioma stem and non-stem cultures, including temozolomide-resistant cell lines, in vitro and in vivo,"* was to investigate how in cancer stem cells (CSC) and non-CSC panels respond *in vitro* to VAL-083 alone or in combination with irradiation (XRT). The study further investigated the activity of VAL-083 in *in vivo* models of drug-resistant GBM in comparison to temozolomide (TMZ).

Data from the *in vitro* portion of the study demonstrate that:

- VAL-083 is highly efficacious against both stem and non-stem GBM cell cultures, including those resistant to temozolomide;
- VAL-083 maintains anti-tumor activity independent of DNA repair enzyme 0-6-methylguanine DNA methyltransferase (MGMT) resistance mechanism; and
- VAL-083 showed an additive effect when combined with radiation in all cultures tested, suggesting that VAL-083 might act as a radiosensitizer in GBM.

The study's *in vivo* results demonstrate that VAL-083 is effective against GBM in significantly extending survival time in intracranial xenograft GBM models in a dose dependent manner, including in GBM xenografts that are traditionally resistant to temozolomide.

"These data further validate the benefits of VAL-083 in the treatment of GBM and support our ongoing Phase 1/2 clinical study with VAL-083 as a treatment for refractory GBM in patients with recurrent disease," stated Jeffrey Bacha, DelMar's president and CEO. "Additionally, because VAL-083's radio-sensitizing effect is seen in MGMT-expressing GBM that is resistant to the current standard of care, temozolomide plus radiation, VAL-083

demonstrates the potential to replace temozolomide as the chemotherapy of choice in chemo-radiation treatment in a majority of newly diagnosed GBM patients whose tumors are known to highly express a repair MGMT."

Mr. Bacha added, "We can see from these results that VAL-083 has the potential to address a significant unmet medical need in GBM patients who fail or are unlikely to respond to today's standard-of-care."

The *in vitro* results show that VAL-083 is an effective inhibitor of all tested primary GBM cultures, irrespective of MGMT status or cell culture condition (stem vs. non-stem). Additionally, VAL-083 caused cell cycle arrest and loss of cell viability in TMZ-resistant cells, and at lower concentrations than TMZ in TMZ-sensitive cells. Furthermore, low dose VAL-083 combined with XRT demonstrated additive radiosensitizing effect in all cultures tested, including those resistant to TMZ.

In the *in vivo* study the data demonstrate that VAL-083 is effective against GBM in extending survival time in intracranial models in a dose-dependent manner. In the first model (U251), median survival time for mice treated with 4 mg/kg VAL-083 was significantly increased to 72 days compared to 48 days for controls ($p<0.0001$). Median survival time for 3 mg/kg VAL-083 was 54 days. In the second model (BT74), preliminary data suggest that VAL-083 treatment increases survival time in mice bearing intracranial BT74 tumors compared to untreated control. BT74 tumors are traditionally resistant to TMZ.

The standard of care for GBM patients is surgical resection followed by TMZ and XRT, but TMZ-resistance has emerged as a significant unmet medical need, as DNA repair enzyme 0-6-methylguanine DNA methyltransferase (MGMT) removes the methyl-group adducts caused by TMZ. VAL-083 is an alkylating agent causing DNA crosslinks at N^7 position of guanine. Because VAL-083's N^7 adducts appear not to be subject to MGMT mediated repair, it may be an effective chemotherapeutic in the treatment of TMZ-resistant GBM. VAL-083 crosses the blood brain barrier and accumulates in brain tumor tissue. Previous studies show that TMZ activity is similar in cancer stem cells (CSC) and their paired non-CSC from primary GBM tissues, and that the activity is MGMT-dependent.

The poster presentation for this study may be found on the DelMar Pharmaceutical website under http://www.delmarpharma.com/products/publications/.

About VAL-083
VAL-083 is a "first-in-class", small-molecule chemotherapeutic. In more than 40 Phase 1 and 2 clinical studies sponsored by the National Cancer Institute, VAL-083 demonstrated safety and efficacy in treating a number of cancers including lung, brain, cervical, ovarian tumors and leukemia. VAL-083 is approved in China for the treatment of chronic myelogenous leukemia and lung cancer and has received orphan drug designation in Europe and the U.S. for the treatment of gliomas. As a potential treatment for glioblastoma, VAL-083's mechanism of action appears to be unaffected by the expression of MGMT, a DNA repair enzyme that causes chemotherapy resistance to front-line treatment with Temodar® (temozolomide). DelMar is currently studying VAL-083 in a Phase I/II clinical trial for patients with refractory glioblastoma multiforme.

About DelMar Pharmaceuticals, Inc.

DelMar Pharmaceuticals, Inc. was founded to develop and commercialize proven cancer therapies in new orphan drug indications where patients are failing or have become intolerable to modern targeted or biologic treatments. The Company's lead drug in development, VAL-083, is currently undergoing clinical trials in the U.S. as a potential treatment for refractory glioblastoma multiforme. VAL-083 has been extensively studied by U.S. National Cancer Institute, and is currently approved for the treatment of chronic myelogenous leukemia (CML) 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 follow us on Twitter @DelMarPharma or Facebook.com/delmarpharma.

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-pharmaceuticals-presents-promising-preclinical-data-on-val-083s-potential-to-treat-temozolomide-resistant-glioblastoma-multiforme-gbm-300068271.html

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