DelMar Pharmaceuticals Presents Additional Data on the Potential of VAL-083 in the Treatment of Temozolomide-Resistant Glioblastoma Multiforme


Dennis Brown, DelMar’s co-Founder and Chief Scientific Officer, presented an abstract entitled, "Dianhydrogalactitol inhibits the growth of glioma stem and non-stem cultures, including temozolomide-resistant cell lines, in vitro and in vivo."

The data from the in vitro portion and the first in vivo segments of the study previously reported at the 2015 AACR annual meeting demonstrated that:

- VAL-083 may be efficacious against both stem and non-stem GBM cell cultures, including those resistant to temozolomide (TMZ);
- VAL-083 maintained anti-tumor activity independent of DNA repair enzyme 0-6-methylguanine DNA methyltransferase (MGMT) resistance mechanism;
- 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; and
- VAL-083 was 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 TMZ.

Data reported at the AACR Advances in Brain Cancer poster session further examined the activity of VAL-083 in in vivo models of drug-resistant GBM in comparison to TMZ. BT74 animal models bearing intracranial human GBM xenograft tumors of either MGMT-positive or TMZ-resistant origin were treated with VAL-083.

The data demonstrated that VAL-083 may be effective against GBM in extending survival time in intracranial models in a dose-dependent manner. In the first model (U251), median survival time for animals 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 in vivo model (BT74) reported yesterday, the additional
data showed that VAL-083 treatment increased survival time in animals bearing intracranial BT74 tumors compared to untreated control. BT74 tumors are traditionally resistant to TMZ.

"VAL-083 has shown encouraging potential to address a significant unmet medical need in GBM patients who fail or are unlikely to respond to today's standard of care. These data continue to further support the potential benefits of VAL-083 in GBM and in our ongoing Phase 1/2 clinical study with VAL-083 as a potential treatment for refractory GBM," stated Jeffrey Bacha, DelMar's president and CEO. "In addition, VAL-083 may offer a potential alternative to the current standard of care, TMZ plus radiation, in newly diagnosed GBM patients whose tumors express high levels of the repair enzyme, O6-methylguanine methyltransferase (MGMT), which is correlated with TMZ resistance and poor patient outcomes."

The standard of care for GBM patients today is surgical resection followed by TMZ and radiation therapy. MGMT-mediated resistance has emerged as a significant unmet medical need. VAL-083 is an alkylating agent whose cytotoxic anti-cancer mechanism is believed to be via the formation of DNA crosslinks at N7 position of guanine. Because these N7 adducts appear not to be subject to MGMT-mediated repair, VAL-83 may be an effective chemotherapeutic in the treatment of TMZ-resistant GBM. VAL-083 has been demonstrated to cross the blood brain barrier and accumulate 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 independent of their MGMT expression.

The poster presentation for this study may be found on the DelMar Pharmaceuticals website under the Scientific Publications & Presentations section.

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 U.S. National Cancer Institutes, 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 multi-center Phase I/II clinical trial for patients with refractory glioblastoma multiforme in accordance with the protocol that has been filed with the U.S. Food and Drug Administration (FDA). Eligible GBM patients must have failed both Avastin® (bevacizumab) and Temodar® (temozolomide) unless either of these therapies was contraindicated. (ClinicalTrials.gov Identifier NCT01478178).

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.

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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.

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