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FDA Grants Second Orphan Designation For VAL-083

FDA Office of Orphan Products Development (OOPD) has granted orphan drug designation for VAL-083 in the treatment of medulloblastoma

VANCOUVER, British Columbia and MENLO PARK, Calif., March 15, 2016 /PRNewswire/ - [DelMar Pharmaceuticals, Inc.](#) (OTCQX: DMPI) ("DelMar" and the "Company"), announced today that the FDA Office of Orphan Products Development (OOPD) has granted orphan drug designation for its lead product candidate, VAL-083, in the treatment of medulloblastoma. The investigational drug candidate previously received an orphan designation for glioblastoma in the United States and in Europe.



VAL-083 is a "first-in-class," small-molecule chemotherapeutic. In more than 40 Phase I and II clinical studies sponsored by the U.S. National Cancer Institute, VAL-083 demonstrated clinical activity against a range of cancers including lung, brain, cervical, ovarian tumors and leukemia both as a single-agent and in combination with other treatments.

"We are pleased to achieve this important regulatory milestone and to continue a collaborative relationship with the FDA and the OOPD as we continue to expand the development of VAL-083," commented Jeffrey Bacha, chairman and CEO of DelMar. "Orphan designation is a major step toward expediting this promising therapy to an additional patient population with few treatment options."

DelMar has been conducting clinical trials with VAL-083 as a potential new treatment for glioblastoma multiforme (GBM), the most common and aggressive form of brain cancer. In September 2015, DelMar announced completion of enrollment in a Phase II clinical trial in refractory GBM. The Company anticipates top-line overall survival data from this trial in the first half of 2016.

Through its research, DelMar has also been exploring the unique cytotoxic mechanism of VAL-083 in order to identify additional indications where VAL-083 may address modern unmet medical needs in the treatment of cancer. In November 2015, DelMar presented new

pre-clinical data in a poster entitled, "*Dianhydrogalactitol (VAL-083) Offers Potential Therapeutic Alternatives in the Treatment of Pediatric Brain Tumors*," at the American Association for Cancer Research (AACR) [Advances in Pediatric Research: From Mechanisms and Models to Treatment and Survivorship Conference](#).

Medulloblastoma is the most common malignant pediatric brain tumor, accounting for 15-30% of all childhood intracranial neoplasms. Although multidisciplinary treatment has improved the 5-year survival rates in children significantly, the prognosis for certain subtypes of medulloblastoma and for recurrent disease remains poor with a median overall survival of less than one (1) year.

In historical NCI-sponsored clinical studies, VAL-083 demonstrated clinical activity against medulloblastoma. In these studies VAL-083 was investigated both as a stand-alone therapy and in combination with other chemotherapeutic regimens. DelMar's recent pre-clinical research demonstrates that VAL-083 is active against medulloblastoma cells with difficult to treat sonic hedgehog (SHH) characteristics and p53 mutations; and VAL-083 in combination with temozolomide completely inhibits self-renewal of pediatric brain cancer stem cells (CSCs).

"Taken together, we believe these data will serve as a basis for our clinical development strategy with VAL-083 in pediatric brain tumors," continued Mr. Bacha. "We plan to continue our discussions with leading clinical investigators in order to undertake the necessary steps to advance VAL-083 into clinical studies as a potential treatment for children suffering from recurrent and difficult-to-treat medulloblastoma subtypes."

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. 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 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+](#). Investor Relations Counsel: Amato & Partners LLC.

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.

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