

TransMolecular Reaches Special Protocol Agreement with FDA for an ¹³¹I-TM601 Phase 3 Trial in Newly Diagnosed Glioblastoma Multiforme Patients

CAMBRIDGE, Mass., - December 2, 2008 – TransMolecular, Inc., a biotechnology company focused on targeted therapies for cancer, announced today that it has reached an agreement with the U.S. Food and Drug Administration (FDA) under the FDA's Special Protocol Assessment (SPA) process for a Phase 3 trial of ¹³¹I-TM601 in patients with newly diagnosed Glioblastoma Multiforme (GBM). Through the SPA, the FDA has agreed that if the ¹³¹I-TM601 Phase 3 study successfully meets its stated endpoints, the design and planned analysis of the trial adequately addresses the objectives necessary to support an efficacy claim in a future NDA submission for regulatory approval.

“The successful negotiation of this special protocol agreement with the FDA is an important milestone for our TM601 tumor targeting platform and the ¹³¹I-TM601 program. We believe this achievement is also a validation of the underlying strength of this platform for multiple oncology applications,” said Michael Egan, President and CEO of TransMolecular. “We are in ongoing discussions with several interested parties to advance this Phase 3-ready compound into this registration trial to complete the data package necessary for licensure and to bring a new therapeutic option to patients affected by this lethal disease.”

TM601 has been validated in a number of preclinical and clinical studies to optimize its potential across a broad tumor targeting platform. TM601 is capable of delivering small and large complex molecules to tumors, an attribute that can increase tumor uptake of therapeutic agents while reducing accumulation in normal tissues. Recently, the TM601 peptide has also been found to have unique anti-angiogenic activity. These platforms are currently being pursued by the company and are the subject of ongoing discussions with several potential partners.

“This SPA is a validation of the regulatory strategy that has guided the clinical development of TM601, and we are particularly pleased with elements of our Phase 3 protocol that, if we are successful, should uniquely position ¹³¹I-TM601 as a very promising therapeutic option for patients with GBM,” commented Susan Stewart, Vice President of Regulatory Affairs at TransMolecular. “The trial will be conducted in patients with newly diagnosed GBM, an area of high unmet medical need. This will enable us to treat patients at initial diagnosis who may derive greater benefit from this targeted therapy than can be obtained by current therapies. In addition, unlike other trials of radiolabeled drugs which require complex radiation dosimetry and customized dosing, the unique tumor-binding specificity and overall safety profile of TM601 supports the use of a fractionated fixed dose approach for all patients under the Phase 3 protocol. We believe that this simplified dosing regimen will deliver a meaningful dose of radiolabeled iodine to these aggressive tumors.”

About the Phase 3 Study:

The randomized Phase 3 study is designed to evaluate the efficacy of ¹³¹I-TM601 in combination with the Standard of Care (SOC) treatment (external beam radiation therapy and temozolomide) compared to SOC treatment alone in adult patients with GBM undergoing surgical resection. The Special Protocol Assessment process provides for a written agreement between the trial's sponsor and the FDA that the design and planned analyses of the clinical

trial can be used in support of regulatory approval. For more information about the Special Protocol Assessment process, see <http://www.fda.gov/cder/guidance/3764fnl.htm> .

TransMolecular has completed or is conducting a number of studies to evaluate TM601-derived therapies to treat patients with various types of cancer. Interim analysis data from a Phase 2 trial of ¹³¹I-TM601 in patients with recurrent malignant glioma showed that the overall survival from the time of recurrence for the highest dosing regimen was estimated at 12.1 months, versus 9.0 months for the lowest dose group. Additionally, no dose-limiting toxicities were observed. In a completed Phase 1 trial, it was confirmed that intravenously-delivered ¹³¹I-TM601 has the ability to cross the blood-brain barrier and target and bind to tumor tissue, as well as to target several other tumor types.

About TM601

TM601 is a novel synthetic peptide derived from scorpion venom, which is highly specific and selective in targeting both primary tumors and metastases both in the periphery and in the central nervous system. TM601 targets and binds to receptors expressed on tumor cells, but not on normal, healthy cells. When radiolabeled TM601 is administered, it is actively and rapidly taken up into these tumor cells, delivering a highly concentrated dose of radiation to kill the tumor cells while sparing nearby healthy cells. TransMolecular is applying the TM601 platform to deliver additional therapeutic agents including novel and currently used chemotherapeutic agents as well as RNAi molecules to tumor cells. The use of the TM601 platform offers the ability to obtain higher chemotherapeutic doses in tumors while limiting uptake of these compounds in normal tissues. High doses of TM601 alone have been found to have robust anti-angiogenic activity in neo-vascular diseases including cancer. These effects of TM601 on the neovasculature have also been validated in animal models of ophthalmic disease, including wet AMD.

About Glioma

In the U.S., an estimated 20,500 new cases of brain and/or nervous system tumors were expected to be diagnosed in 2007. Of primary brain tumors, malignant glioma is the most common tumor type and is the second most common cause of cancer-related mortality in the 15-to-44 age group. In patients with grade IV glioma, or glioblastoma multiforme, the median survival from the time of diagnosis is approximately one year. Despite over twenty-five years of intensive research and a variety of chemotherapy, radiotherapy, and surgical approaches, the prognosis for these tumors has not changed significantly. Malignant glioma remains one of the most aggressive and difficult-to-treat cancers.

About TransMolecular, Inc.

TransMolecular, Inc. is a privately held, venture capital backed biotechnology company committed to discovering, developing and commercializing novel and proprietary products to diagnose and treat cancers that have inadequate treatment alternatives. TransMolecular's product pipeline is based on the TM601 platform that employs a therapeutically active polypeptide derived from scorpion venom. The company is currently exploring the use of this platform for broad applications to diagnose and treat cancers and other human diseases. More information can be found at www.transmolecular.com.

This press release contains forward-looking statements. The Company wishes to caution the reader of this press release that actual results may differ from those discussed in the forward-looking statements and may be adversely affected by, among other things, risks associated with litigation, clinical trials, the regulatory approval process, reimbursement policies, commercialization of new technologies, intellectual property, and other factors.

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