

# TransMolecular Reports Positive Phase 2 Data from Study of <sup>131</sup>Iodine Radiolabeled TM-601 in Recurrent Glioma

## -Interim data demonstrates promising overall survival rates and no dose-limiting toxicities-

**CAMBRIDGE, MA** – November 19, 2007 – TransMolecular, Inc., a biotechnology company focused on targeted therapies for cancer, today announced the presentation of positive Phase 2 interim results for the intracavitary delivery of its anti-cancer compound <sup>131</sup>I-TM-601 in recurrent malignant glioma at the Society for Neuro-Oncology's 12th Annual Scientific Meeting in Dallas, TX. An interim efficacy analysis from the ongoing, open-label Phase 2 safety and efficacy study demonstrated 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 the dose-escalation phase of the study. The abstract was presented by lead author Dr. Burt Nabors, M.D., of the University of Alabama at Birmingham in a poster session on November 17, 2007.

"Glioma is an aggressive, poor-prognosis cancer, and patients with this disease unfortunately have very limited medical options and are faced with poor survival rates," said Dr. Nabors. "I am encouraged by this interim data from the intracavitary delivery of TM-601, as it suggests a significant survival benefit associated with the highest dosage of the radiolabeled peptide, and it also reveals its favorable safety and toxicity profiles."

"The positive interim results from this study build on a growing body of evidence supporting our TM-601 program, which includes data we presented last month at ASTRO demonstrating that the intravenous formulation could cross the blood-brain barrier and successfully bind to tumor tissue," stated Michael Egan, President and Chief Executive Officer of TransMolecular. "The platform we are building for this compound has produced additional therapeutic opportunities, and we have filed protocols with FDA for a Phase 2 intravenous trial in glioma as well as a Phase 1 trial in malignant glioma with non-radiolabeled TM-601, both of which we expect to initiate in the near-term. We are also planning additional trials in other cancers."

In the initial dose escalation phase of the trial, 15 patients were treated sequentially in four dose cohorts with escalating doses of radiolabeled TM-601: 20 mCi-0.4 mg x 3, 30 mCi-0.6 mg x 3, 40 mCi-0.8 mg x 3, and 40 mCi-0.8 mg x 6. Because no dose-limiting toxicities were observed in this part of the study, the study has been advanced into a randomized phase in which patients receive either three or six doses of radiolabeled TM-601 administered at 40 mCi-0.8 mg on a weekly basis. A total of 56 evaluable patients were included in the interim efficacy analysis, from both the dose-escalation phase and the randomized phase of the study. An additional three patients were included in the survival analysis on an Intention-to-Treat basis.

The pooled survival analysis of all 59 patients yielded a median overall survival of 9.4 months. Patients treated at the two highest dosing regimens (40 mCi-0.8 mg for 3 or 6 doses) also had median overall survival rates of 9.4 months. However, a comparison of overall survival between the 3 dose and 6 dose groups demonstrated the superiority of the 6 dose regimen, with the 6 dose regimen resulting in an estimated survival of 12.1 months, versus an estimated 9.0 months for the 3 dose group.

#### About TM-601

TM-601 is a synthetic version of chlorotoxin, a naturally occurring peptide derived from scorpion venom, which is highly specific in targeting both primary tumors and metastases. TM-601 targets and binds to receptors expressed on tumor cells but not on normal, healthy cells. As TM-601 binds primarily with the tumor cell receptor sites, it also delivers a targeted dose of radiation, killing the tumor cell without affecting nearby healthy cells. The mechanism-of-action of TM-601 also suggests that it may affect a tumor's ability to grow and spread without added radiation, so its therapeutic potential as a non-radiolabeled peptide is also being explored. The Company's robust development plan for TM-601 reflects its broad platform potential for multiple applications in cancer. The FDA has granted it orphan drug status for patients with high-grade glioma, as well as a Fast Track designation.

## **About Glioma**

Glioma is a highly invasive, rapidly spreading form of brain cancer that is currently resistant to surgical or medical treatment. Among the 36,000 primary brain tumors reported in the U.S. each year, more than 17,000 are diagnosed as high-grade gliomas. Gliomas can occur at any time in life, from childhood to old age. About half of patients with high-grade glioma die within the first year of diagnosis.

## 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 a protein platform that employs therapeutically active polypeptides 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 <a href="https://www.transmolecular.com">www.transmolecular.com</a>.

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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