



## **TransMolecular Receives Orphan Drug Designation for Non-radiolabeled TM601 for the Treatment of Malignant Glioma**

**CAMBRIDGE, MA** – January 7, 2008 – TransMolecular, Inc., a biotechnology company focused on targeted therapies for cancer, today announced that the FDA has granted Orphan Drug Designation for the non-radiolabeled version of its anti-cancer compound TM601, which is currently entering clinical trials for the treatment of malignant glioma. The company had previously received Orphan designation for the radiolabeled version, <sup>131</sup>I-TM601, which recently completed patient enrollment in a Phase 2 clinical trial in glioma and a Phase 1 trial in multiple tumor types.

“We are pleased to receive orphan drug status for TM601 in malignant glioma,” stated Michael Egan, President and Chief Executive Officer of TransMolecular. “The TM601 platform has performed very well in recent Phase 1 and 2 clinical trials, showing specific tumor targeting in both primary and metastatic disease of multiple tumor types. This adds to a strong clinical rationale supporting its therapeutic promise, and we look forward to initiating Phase 1 clinical trials with the non-radiolabeled form of this drug candidate in malignant glioma. This designation is part of TransMolecular’s strategy to advance this program so that patients with this poor-prognosis disease may eventually have a new treatment option available to them.”

The FDA grants Orphan Drug Designation to promising products that address rare diseases affecting fewer than 200,000 Americans annually. If non-radiolabeled TM601 receives FDA approval for malignant glioma, this designation will entitle TransMolecular to exclusive marketing rights for the compound for the treatment of malignant glioma for seven years following the NDA approval. Orphan Drug Designation provides financial and regulatory incentives for companies pursuing less common diseases.

### **About TM601**

TM601 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. TM601 targets and binds to receptors expressed on tumor cells but not on normal, healthy cells. As TM601 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 data obtained from preclinical and clinical data also suggest that native TM601 may affect a tumor’s ability to grow and spread without added radiation, so the therapeutic potential as a non-radiolabeled peptide is also being explored. The Company’s robust development plan for TM601 reflects its broad platform potential for multiple applications in cancer. The FDA has granted it orphan drug status for patients with high-grade and malignant glioma, as well as a Fast Track designation.

### **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 III anaplastic glioma, the median survival is three-to-five years; however, median survival in patients with grade IV glioma or glioblastoma multiforme is less than a 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. Primary brain tumors remain 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 a protein 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](http://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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