TransMolecular Receives Orphan Drug Designation for ^{131}I-TM601 for the Treatment of Melanoma

CAMBRIDGE, MA – December 22, 2008 – TransMolecular, Inc., a biotechnology company focused on targeted therapies for cancer, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation for its anti-cancer compound ^{131}I-TM601 for the treatment of Stage IIb-IV melanoma. The drug candidate is currently in a Phase 1/2 clinical trial for the treatment of recurrent malignant melanoma. The company had previously received Orphan designation for ^{131}I-TM601 in malignant glioma, as well as for the non-radiolabeled version of TM601 for the treatment of malignant glioma.

"The receipt of our third Orphan Drug Designation is a result of our robust regulatory and clinical development strategy for the TM601 tumor-targeting platform," said Michael Egan, President and Chief Executive Officer of TransMolecular. "We are pleased that this designation represents another step toward our goal of delivering a new therapy to patients battling this difficult disease. Further, it demonstrates recognition of the broad applicability and promise of this platform across multiple oncology applications."

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. In a completed Phase 1 trial it was confirmed that intravenously-delivered ^{131}I-TM601 has the ability to target and bind to tumor tissue in multiple solid tumor types, as well as cross the blood-brain barrier to target tumors in the brain. TransMolecular has obtained an agreement with the FDA through a Special Protocol Assessment (SPA) for conduct of a Phase 3 trial of ^{131}I-TM601 in patients with newly diagnosed Glioblastoma Multiforme (GBM). TransMolecular's tumor-targeting platform is currently being pursued by the company and is the subject of ongoing discussions with several potential partners.

In addition to its tumor-targeting capability, non-radiolabeled TM601 has demonstrated anti-angiogenic activity at higher doses. The unique anti-angiogenic method-of-action of TM601 is now being investigated in a Phase 1 clinical trial in patients with recurrent glioma.

The FDA grants Orphan Drug Designation to promising products that address rare diseases affecting fewer than 200,000 Americans annually. If ^{131}I-TM601 receives FDA approval for melanoma, this designation will entitle TransMolecular to exclusive marketing rights for the compound for the treatment of melanoma for seven years following an NDA approval. Orphan Drug Designation provides financial and regulatory incentives for companies pursuing less common diseases.

About TM601

TM601 is a novel, wholly synthetic peptide originally derived from scorpion venom, which is highly specific and selective in targeting both primary tumors and metastases 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 potential 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 age-related macular degeneration (AMD).

About Melanoma
In the U.S., an estimated 60,000 people are diagnosed each year with melanoma, the deadliest form of skin cancer. In 2008, 8,000 people are expected to die from the disease. The incidence of new cases has more than doubled in the past 30 years. There are no currently approved therapies for metastatic melanoma that have demonstrated improved survival for patients.

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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Contacts:

TransMolecular:
Michael Egan
President and CEO
(617) 995-3050

Media:
Jennifer Greenleaf-Conrad
MacDougall Biomedical Communications
(781) 235-3060
jconrad@macbiocom.com