



TransMolecular, Inc. A Neuroscience Biotechnology Company

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FDA Grants TransMolecular Orphan Drug Designation for ¹³¹I-TM-601 for Use by Glioma Patients

BIRMINGHAM, Ala.--TransMolecular, Inc. today announced that it has received Orphan Drug Designation from the U.S. Food and Drug Administration for its Investigational New Drug, ¹³¹I-TM-601, to treat patients suffering from glioma, one of the most deadly forms of brain cancer.

¹³¹I-TM-601 is a radiopharmaceutical anti-cancer drug containing a synthetic version of a substance derived from scorpions called chlorotoxin. The Food and Drug Administration approved TransMolecular's IND application to begin a Phase I/II clinical study of the drug in humans in January 2002.

Last week, TransMolecular announced the start of a multi-center clinical study to evaluate the safety and tolerability of a single dose of ¹³¹I-TM-601, as well as overall tumor response rate in an initial study group of 18 patients. In pre-clinical studies, TransMolecular scientists determined that ¹³¹I-TM-601 was able to extend survival in a mouse model that mimicked human brain tumors.

"We are extremely pleased by the FDA's action in granting orphan drug designation for ¹³¹I-TM-601, an important step in bringing this drug to market," says Matthew A. Gonda, Ph.D., TransMolecular president and CEO. "Therapeutic options for glioma patients are rather limited. Orphan drug designation could greatly assist us in the clinical development and marketing of our new drug candidate for patients suffering from this devastating and deadly disease."

TM-601 is based on chlorotoxin sequences that have evolved to precisely locate and bind to their receptor, which is abnormally expressed on tumor cells, but is not expressed on normal cells. The chlorotoxin sequences in ¹³¹I-TM-601 are the guidance system that delivers ¹³¹I, the radioactive therapeutic payload, to its target, precisely killing the tumor cells. No toxicities have been observed with TM-601 administration in pre-clinical animal studies.

The Orphan Drug Designation is provided exclusively for products that treat a disease affecting fewer than 200,000 persons in the U.S., to encourage research and testing. The scientific rationale for use of the compound in treating the disease must

also pass FDA review. Potential benefits from orphan drug designation include seven years of market exclusivity upon marketing approval, tax credits for related clinical research expenses, the availability of grant assistance, and clinical development assistance from the FDA.

Glioma is highly invasive, sending cancerous cells throughout the brain and spinal cord. Surgical techniques fail to eradicate the tumor and other adjuvant therapies are inadequate. Brain cancers are among the most difficult and expensive cancers to treat. About 36,000 primary brain tumors are reported in the U.S. each year; of these, more than 17,000 are diagnosed with high-grade gliomas. About half of these patients die within the first year, according to the American Cancer Society. There is a need for safe, more effective treatments for glioma.

About TransMolecular, Inc.

TransMolecular, Inc. founded in 1996, is a privately held neuroscience biotechnology company committed to discovering, developing and commercializing novel and proprietary products to diagnose and treat disorders and diseases of the central nervous system having inadequate pharmaceutical alternatives, including cancer and pain. The company's corporate office and R&D laboratory are located in Birmingham, Ala. For more information, visit www.transmolecular.com.