



# Otsuka Maryland Research Institute, Inc.

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## FOR IMMEDIATE RELEASE

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## OTSUKA MARYLAND RESEARCH INSTITUTE, INC. GRANTED FAST TRACK DESIGNATION FOR TOLVAPTAN IN PKD

**ROCKVILLE, MD (February 23, 2006)** – Otsuka Maryland Research Institute, Inc. (OMRI) announced that the Food and Drug Administration has granted Fast Track designation to their product tolvaptan for the treatment of Autosomal Dominant Polycystic Kidney Disease (ADPKD). Fast track programs are designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs.

In citing reasons for granting tolvaptan the Fast Track designation, the agency noted that currently, there is no effective therapy for patients with ADPKD. Tolvaptan is being evaluated as a preventive product for both a serious manifestation of the disease, increased renal size, and the secondary complications such as hypertension, proteinuria and renal pain. The FDA noted that OMRI plans to conduct efficacy studies in patients with ADPKD, and it is believed that tolvaptan might be effective in the treatment of ADPKD based on what is known regarding the pathophysiology of the disease, the known mode of action of tolvaptan, and the results from nonclinical animal model studies.

In Phase II studies with PKD subjects, tolvaptan has been associated with side effects that include increased thirst and urination.

OMRI has completed several Phase II clinical trials with tolvaptan in patients with ADPKD, and is beginning global Phase III clinical trials. ADPKD is characterized by the progressive enlargement of focal cysts in both kidneys. Patients with ADPKD suffer from a variety of other morbidities including chronic pain, hypertension, renal hemorrhage and infection. Over 50% of ADPKD patients eventually progress to end-stage renal disease, resulting in dialysis, transplantation, and their associated morbidity and mortality.

For more information about Otsuka's PKD program, please contact 1.866.712.5837.

## **About Otsuka Maryland Research, Inc. (OMRI)**

Otsuka Maryland Research Institute, Inc. is involved in conducting all phases of clinical research and development of innovative healthcare products to address unmet medical needs. OMRI is well established in the scientific community as a globally focused organization that plays a leadership role in the research and development of Otsuka's ethical healthcare products. The Company is dedicated to the improvement of the quality of human life and health of patients around the world. OMRI is part of the Otsuka Pharmaceutical Group. For additional information, visit [www.otsuka.com](http://www.otsuka.com).

Founded in 1964, Otsuka Pharmaceutical Co., Ltd. is a healthcare company with the mission statement: "Otsuka — people creating new products for better health worldwide." Otsuka researches, develops, manufactures and markets innovative, original products, focusing its core businesses on pharmaceutical products for the treatment of disease and consumer products for the maintenance of everyday health. The Otsuka Pharmaceutical Group comprises 81 companies and employs approximately 26,000 people in 16 countries and regions worldwide. Otsuka and its consolidated subsidiaries earned US \$6.2 billion in annual revenues in fiscal 2004.