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### **FOR IMMEDIATE RELEASE**

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### **Poster on Investigational Otsuka Product Receives Presidential Poster Award from American College of Gastroenterology**

*Award Recognizes Poster on OPC-6535 in Development for Ulcerative Colitis*

**ROCKVILLE, MD. — November 9, 2004** Otsuka Maryland Research Institute, Inc., (OMRI) is pleased to announce that a poster on its investigational product in development for ulcerative colitis (UC), OPC-6535, has been selected as a winner of the American College of Gastroenterology (ACG)'s Presidential Poster Award. The posters receiving this award accumulated scores in the top five percent of the 808 posters submitted for the ACG Annual Meeting, taking place October 29 – November 3 in Orlando, Florida.

The Otsuka Maryland Research Institute, Inc. (OMRI) began phase III clinical trials in 2003 on the compound OPC-6535 to determine its safety and effectiveness in treating ulcerative colitis. Stephen B. Hanauer, MD, Professor of Medicine and Clinical Pharmacology, Director, Section of Gastroenterology and Nutrition, University of Chicago Medical Center, serves as the Head of the Otsuka North American Scientific Advisory Board for the OPC-6535 clinical trials. He is also the lead author of the award winning poster, titled "Once-Daily, Oral OPC-6535 in the Treatment of Active Ulcerative Colitis: Effect of Concomitant 5-ASA Use."

"We are honored that Dr. Hanauer's poster on OPC-6535 has received this distinguished award from the American College of Gastroenterology and congratulate all of the investigators involved," said Yoichi Nishinakamura, Chairman, CEO, President and COO, Otsuka Maryland Research Institute, Inc. "We look forward to continuing to learn more about this investigational product that may offer help to people who suffer from this debilitating disease."

The recent randomized, multi-center, placebo-controlled trial of 186 subjects with mild to moderate UC demonstrated improvement in mean Disease Activity Index (DAI) scores, and other endpoints with OPC-6535. The aim of the current investigation was to compare treatment responses in subjects taking OPC-6535 with and without concomitant 5-ASA. Results indicated that baseline DAI scores were comparable between 5-ASA and non-5-ASA users.

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“According to the abstract we presented, OPC-6535 data show promise as both primary and adjunctive (to 5-ASA) therapy in the treatment of ulcerative colitis, especially in patients with greater disease severity,” said Dr. Hanauer. “We are excited about continuing investigating OPC-6535 to further assess how it may play a role in treating this disease that affects hundreds of thousands of Americans.”

Adverse events reported in clinical studies with OPC-6535 included headache, nausea, dizziness, abdominal pain, vomiting, indigestion, flu, sweating, chills, weakness and gas.

**About Otsuka Maryland Research Institute, Inc.**

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 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 products, focusing its core businesses on pharmaceutical products for the treatment of disease and consumer products for the promotion of everyday health. The Otsuka Pharmaceutical Group includes 73 enterprises around the world, employs 23,000 people, and has total annual revenues of \$4.4 billion.

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