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OTSUKA'S ADACOLUMN® DEVICE TO ENTER PIVOTAL STUDY IN ULCERATIVE COLITIS

Pivotal study initiated to investigate Adacolumn Device's safety and effectiveness

ROCKVILLE, MD, April 7, 2004 – Following FDA review of an IDE submitted by Otsuka America Pharmaceutical, Inc., a pivotal study of the Adacolumn Device for treatment of Ulcerative Colitis is being initiated. This pivotal study will evaluate the Safety and Effectiveness of the Adacolumn Device for the treatment of Moderate to Severe Ulcerative Colitis and will enroll 168 subjects at major clinical sites in United States and Canada.

"We are excited to move forward with Adacolumn and begin enrolling subjects to evaluate the device for use in the treatment of ulcerative colitis," said Hiromi Yoshikawa, Chairman and CEO, Otsuka America Pharmaceutical, Inc. "Otsuka has a long global history of dedication to gastrointestinal diseases."

The Adacolumn device operates as an adsorptive apheresis, an infusion process by which certain cellular or fluid elements of a patient's own blood are removed. The device returns the remaining blood to the patient. Otsuka America Pharmaceutical, Inc. (OAPI) has licensed Adacolumn from Japanese Immunoresearch Laboratories Co., Ltd. (JIMRO) for development in the U.S.

Based on clinical trial experience in Japan and Europe, reported adverse events include headache, dizziness/vertigo/lightheadedness, abdominal pain, pharyngitis/sore throat, tiredness/fatigue/malaise, fever, worsening anemia or low red blood cell count, nausea/vomiting, and bruising at sites where needles are inserted.

Ulcerative colitis is a chronic digestive disorder, affecting some 500,000 Americans, according to the Crohn's and Colitis Foundation of America. Ulcerative Colitis inflames the inner lining of the colon (large intestine) and the rectum. Symptoms range from mild to severe, including persistent diarrhea, abdominal pain, rectal bleeding, fever, weight loss, skin or eye irritations, and delayed growth and sexual maturation in children. It is medically incurable and its cause is unknown.

Otsuka America Pharmaceutical, Inc. is a successful, innovative and fast-growing health care company that commercializes Otsuka-discovered and other product opportunities in North America, with a strong focus on and commitment to neuroscience, cardiovascular and gastrointestinal treatments. OAPI is dedicated to improving patient's health and the quality of their lives. The company is part of the Otsuka Pharmaceuticals Group, a privately-held conglomerate comprised of 51 businesses and more than 22,000 employees worldwide.

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