



Otsuka America Pharmaceutical, Inc.

2440 Research Boulevard
Rockville, Maryland 20850
Phone: 301.990.0030
Fax: 301.990.0035
www.otsuka.com

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Contact:

Debra Kaufmann
Otsuka America Pharmaceutical, Inc.
240.683.3568
debra.kaufmann@otsuka.com

Donna H. Wright
240.994.0829
donnahwright@hotmail.com

Multiple Studies at DDW Report on Adacolumn® Apheresis Device in Treating Inflammatory Bowel Disease Otsuka America Pharmaceutical, Inc. Investigational Device featured in DDW Poster of Distinction

Chicago, IL, May 18, 2005 – Eleven studies reporting clinical outcomes in patients treated with the Adacolumn® Apheresis System (Adacolumn®) in Japan and Europe with inflammatory bowel disease (IBD) of various stages and severity were presented at Digestive Disease Week® 2005 (DDW®). The Adacolumn is a non-pharmacological extra-corporeal adsorptive device that removes active granulocytes and monocytes from blood circulation. Adacolumn is in pivotal studies for ulcerative colitis and Crohn's disease in the United States and in Canada.

Inflammatory Bowel Disease (IBD), encompassing both ulcerative colitis and Crohn's disease, is an often debilitating set of health conditions that affect approximately one million men, women and children in the United States. There is currently no medical cure, although surgery abates some cases of ulcerative colitis. Current treatment consists of corticosteroids, aminosalicylates, immunomodulators, antibiotics, and biologic therapies separately or in combination, tailored to the severity of the disease, the amount or section of the digestive tract affected, and whether the disease is active or in remission for each individual patient.

Granulocyte, Monocyte/Macrophage Apheresis for IBD in Clinical Practice, Clinical Results from the First 100 Patients Treated in Scandinavia, lead author Tryggve Ljung, was named a DDW Poster of Distinction by the American Gastroenterological Association. This designation is given to only the top 10% of abstracts received for the meeting. The study showed a 68% response rate including clinical remission in 44 patients and response in 24. Complete steroid withdrawal was attained in 27 out of 50 patients who were on steroids before the study.

Another study, *Adacolumn® Apheresis Reduces Relapse Rates in Patients with IBD at Significant Risk of Clinical Relapse*, lead author L. Maiden, reported on the time between acute flare-ups and morbidity associated with a severe clinical relapse when using fecal calprotectin level as a guide to start the apheresis treatment in asymptomatic patients.

Hiroyuki Hanai conducted a study titled *Correlations Between Peripheral Blood Neutrophils, Faecal Calprotectin and Intestinal Inflammation in Patients with Active Ulcerative Colitis* in which he supported the use of fecal calprotectin for guiding the treatment of active ulcerative colitis. An oral presentation of Dr. Hanai's study was presented by Dr. Abby R. Saniabadi.

Long-Term Follow-Up of Leukocyte Adsorptive Apheresis (LAA) Treatment in Patients (PTS) with Moderately Active Steroid-Dependent Ulcerative Colitis (UC), lead author Prof. Robert Loeffberg reported results of treatment in pilot studies with Adacolumn, including data on clinical remission in ulcerative colitis (UC) patients with chronic disease that had not responded to intensive corticosteroid treatment and the clinical effects after treatments ended.

“Individually and collectively these studies demonstrate the potential of the Adacolumn® Apheresis Device to reduce symptoms in patients’ who suffer with inflammatory bowel disease,” said Prof. Loeffberg.

Based on clinical trial experience in Japan and Europe, frequently 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.

Abstracts of each of these ten studies appear in the April 2005 supplement to the American Gastroenterological Association’s journal *Gastroenterology*, GI’s leading peer-reviewed journal committed to publishing clinical and basic studies of all aspects of the digestive system, including the liver and pancreas as well as nutrition.

About DDW

Digestive Disease Week (DDW) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA), the American Society for Gastrointestinal Endoscopy (ASGE) and Society for Surgery of the Alimentary Track (SSAT), DDW takes place May 14-19, 2005 in Chicago. The meeting showcases approximately 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology.

About Otsuka America Pharmaceutical, Inc. (OAPI)

Otsuka America Pharmaceutical, Inc. (OAPI) is a successful, innovative, fast-growing healthcare company that commercializes Otsuka-discovered and other product opportunities in North America. OAPI is dedicated to improving patients’ health and the quality of human life. The company is part of the Otsuka Pharmaceutical Group, which is comprised of 73 companies and approximately 23,000 people around the world. With 39 consolidated subsidiaries employing approximately 17,000 people, Otsuka earned US \$4.4 billion in consolidated annual revenues in fiscal 2003. For additional information, please visit www.otsuka.com.

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