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American Gastroenterological Association

Infliximab may help prevent post-operative Crohn's disease recurrence

Studies indicate most therapies show little benefit

Bethesda, MD (Feb. 1, 2009) – The administration of infliximab after intestinal resective surgery was found to be effective at preventing endoscopic and histological recurrence of Crohn's disease, according to a new study in *Gastroenterology*, the official journal of the American Gastroenterological Association (AGA) Institute. To date, there have been no randomized controlled trials evaluating infliximab for postoperative Crohn's disease prevention.

"Our study provides strong evidence that infliximab is effective at preventing endoscopic, clinical and histological postoperative recurrence of Crohn's disease, and provides a rationale for aggressive postoperative chemoprevention with biologic therapy," said Miguel Regueiro, MD, of the University of Pittsburgh Medical Center. "We are encouraged by our findings, which warrant future study of the duration of post-operative infliximab maintenance and appropriate endoscopic follow up."

Crohn's disease is an inflammation and ulceration process that occurs in the deep layers of the intestinal wall and commonly recurs after intestinal resection. Despite the advent of immunomodulator therapy, approximately 75 percent of Crohn's disease patients require an intestinal resection for complications.

Researchers randomly assigned 24 Crohn's disease patients who had undergone ileocolonic resection to receive intravenous infliximab (5 mg/kg), administered within four weeks of surgery and continued for one year, or placebo. The study's research team elected to use endoscopic recurrence at one year as the primary study endpoint. Secondary endpoints were clinical recurrence and remission and histological recurrence.

At one year, the rate of endoscopic recurrence was significantly lower in the infliximab group (9.1 percent) compared to the placebo group (84.6 percent). There was a non-significant

higher proportion of patients in clinical remission in the infliximab group (80 percent) compared to the placebo group (53.8 percent). The histological recurrence rate at one year was significantly lower in the infliximab group (27.3 percent) compared to the placebo group (84.6 percent).

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Visit www.gastro.org/patient for more patient information about Crohn's disease.

About the AGA Institute

The American Gastroenterological Association (AGA) is dedicated to the mission of advancing the science and practice of gastroenterology. Founded in 1897, the AGA is one of the oldest medical-specialty societies in the U.S. Comprised of two non-profit organizations—the AGA and the AGA Institute—our more than 16,000 members include physicians and scientists who research, diagnose and treat disorders of the gastrointestinal tract and liver. The AGA, a 501(c6) organization, administers all membership and public policy activities, while the AGA Institute, a 501(c3) organization, runs the organization's practice, research and educational programs. On a monthly basis, the AGA Institute publishes two highly respected journals, *Gastroenterology* and *Clinical Gastroenterology and Hepatology*. The organization's annual meeting is Digestive Disease Week®, which is held each May and is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. For more information, please visit www.gastro.org.

About Gastroenterology

Gastroenterology, the official journal of the AGA Institute, is the most prominent scientific journal in the specialty and is in the top 1 percent of indexed medical journals internationally. The journal publishes clinical and basic science studies of all aspects of the digestive system, including the liver and pancreas, as well as nutrition. The journal is abstracted and indexed in Biological Abstracts, CABS, Chemical Abstracts, Current Contents, Excerpta Medica, Index Medicus, Nutrition Abstracts and Science Citation Index. For more information, visit www.gastrojournal.org.

