

## Most Patients With Ulcerative Colitis Remain in Remission After 12 Months of MMX Mesalamine Therapy

PHILADELPHIA - November 2, 2007 - The majority of ulcerative colitis patients with both left-sided and extensive disease remain in remission after receiving once-daily mesalamine with multimatrix system (MMX mesalamine; *Lialda*, Shire US, Inc) as maintenance therapy for 12 months, a study finds. In a related study, MMX mesalamine was efficacious for remission maintenance of both mild and moderate ulcerative colitis.

The first study was presented here at the American College of Gastroenterology 2007 Annual Scientific Meeting and Postgraduate Course by Gary Lichtenstein, MD, a professor of medicine at the University of Pennsylvania School of Medicine and the director of the Center for Inflammatory Bowel Diseases at the Hospital of the University of Pennsylvania, both in Philadelphia.

The study was a post hoc analysis of 2 long-term, phase 3 trials of MMX mesalamine. The research looked at the efficacy of 2.4 g MMX mesalamine given once daily or 1.2 g given twice daily for 12 months in maintaining remission in patients with active, mild to moderate ulcerative colitis who had achieved clinical and endoscopic remission in the 2 phase 3 trials.

The maintenance phase efficacy population included 451 patients, of whom 450 had known extent of disease. In the evaluable efficacy population, 12-month remission rates were 67.0% in patients with left-sided disease at baseline and 64.7% in patients with extensive disease at baseline.

"About two thirds of patients in both groups, with left-sided or extensive colitis, were in remission at 12 months, suggesting that disease extent did not play a role in whether a patient would achieve remission or not," Dr. Lichtenstein told *Medscape Gastroenterology*. "That's very important because many times we don't know the disease extent of patients clinically when we treat them."

In addition, remission rates after 12 months were not significantly different in patients receiving MMX mesalamine 2.4 g once daily or 1.2 g twice daily: 65.5% for patients with left-sided ulcerative colitis at baseline who received 2.4 g once daily (n = 171) and 68.4% for patients with left-sided ulcerative colitis who received MMX mesalamine 1.2 g twice daily (n = 177;  $P = .570$ ). Among patients with extensive ulcerative colitis at baseline, the remission rates were 60.4% (n = 48) for the once-daily MMX mesalamine group and 68.5% (n = 54) for the twice-daily group ( $P = .393$ ).

"We look at disease activity and disease extent, so the disease extent makes no difference here. One size fits all, is what I say," Dr. Lichtenstein said.

The study results are helpful because they offer patients "a potentially less burdensome way of taking the medication," said Daniel Leffler, MD, a clinical fellow in the division of gastroenterology at Beth Israel Deaconess Medical Center in Boston, Massachusetts, who attended the session but was not associated with the study.

"Since we know compliance is one of the main factors in predicting poor outcomes and relapse, anything that helps people take what they're supposed to take is going to be an important step forward in therapy. It's the same drug we've had before, but it's just the fact that the dosing modality is a little bit easier. It's a helpful thing to have in our formulary."

A related study investigated the effect of baseline disease severity on long-term remission rates in patients with quiescent ulcerative colitis who received MMX mesalamine 2.4 g once daily as maintenance therapy.

Patients with mild to moderate ulcerative colitis who had achieved clinical and endoscopic remission during treatment with MMX mesalamine could choose to be randomly assigned to MMX mesalamine 2.4 g once daily or 1.2 g twice daily for 12 months.

The study included several patients who did not meet the strict protocol-defined remission criteria but who were considered to be well enough to receive maintenance treatment, noted lead investigator Remo Panaccione, MD, director of the Inflammatory Bowel Disease Clinic at the University of Calgary, Alberta, Canada.

The maintenance phase efficacy population included 451 patients, of whom 166 (36.8%) had mild disease and 285 (63.2%) had moderate disease at baseline. Twelve-month remission rates were 70.5% (117/166) for patients with mild disease at baseline, and 64.2% (183/285) for patients with moderate disease at baseline.

Remission rates were not significantly different in patients receiving MMX mesalamine 2.4 g once daily or 1.2 g twice daily for mild (69.0% vs 72.2%;  $P = .653$ ) or moderate (61.4% vs 66.7%;  $P = .352$ ) disease.

Dr. Panaccione concluded that MMX mesalamine 2.4 g once daily or 1.2 g twice daily is efficacious for the maintenance of remission of both mild and moderate ulcerative colitis.

MMX mesalamine's once-daily formulation "is the least pill burden that patients have to take, so when we look at adherence and compliance of patients in taking medication, this is clearly one of the major factors that enables them to continue taking medication, particularly when they're in remission," Dr. Lichtenstein concluded. "This has really been a major advance for patients when it comes to mesalamine treatment."

Both studies received financial support from Shire Pharmaceuticals, the maker of MMX mesalamine (*Lialda*).