

## Long-term Safety Data on MMX Mesalamine in Ulcerative Colitis

Data from study 303, a multicenter, phase III, open-label, 12-month extension study evaluating the safety and efficacy of MMX mesalamine (Lialda, Shire) in ulcerative colitis (UC) patients, were published in the July issue of *Gut*. A total of 459 patients were examined (246 patients from parent studies 301 and 302, the 8-week, phase III, placebo-controlled trials examining the induction of remission with MMX mesalamine, and 213 patients who received an additional 8 weeks of MMX mesalamine 4.8 g/day to induce remission). Patients were randomized to receive MMX mesalamine dosed once (2.4 g/day) or twice daily (1.2 g twice daily) as maintenance therapy for 12 months.

The authors found that 37.9% (174) of the 459 patients experienced 384 adverse events, which were mostly mild or moderate. Eighteen patients (3.9%), 9 in each group, had 22 serious adverse events (10 in the once-daily group and 12 in the twice-daily group). Most serious adverse events were gastrointestinal and experienced by 5 patients in the once-daily group and 4 patients in the twice-daily group. At 12 months, 64.4% (efficacy population, n=451) of patients in the once-daily group and 68.5% of patients in the twice-daily group were in clinical and endoscopic remission ( $P=.351$ ). Furthermore, at 12 months, 88.9% of the once-daily group and 93.2% of the twice-daily group had maintained clinical remission and were considered relapse-free. The authors concluded that MMX mesalamine 2.4 g/day given once- or twice-daily showed a good safety profile, was well tolerated, and was effective as maintenance therapy, and that once-daily dosing could achieve high clinical and endoscopic remission rates.

## Oral Sodium Phosphate Bowel Preparation and Fasting Prior to Capsule Endoscopy

Led by Marie-George Lapalus, MD, of the Hopital Edouard Herriot in Lyon, France, researchers evaluated the use of oral sodium phosphate bowel preparation prior to capsule endoscopy examination of the small bowel in patients with obscure gastrointestinal bleeding. The results of this prospective, multicenter, controlled, randomized, blinded study were published in the June issue of *Gastrointestinal Endoscopy*. Between December 2004 and February 2006, 129 patients (53 men and 76 women; median age, 56.9 years) with obscure gastrointestinal bleeding were randomized into two groups: group A (n=64), in which capsule endoscopy was performed after an 8-hour fast-

ing period; or group B (n=63), in which patients drank 2 doses of 45 mL sodium phosphate prior to undergoing capsule endoscopy. The quality of the images taken via capsule was independently evaluated by blinded researchers at five segments of the small bowel: the duodenum, jejunum, middle small bowel, ileum, and distal ileum. The presence of bubbles, liquid, and the rate of visibility were used to assess bowel cleanliness and visibility.

Of the patients, 127 were analyzed, as 2 were unable to swallow the capsule. No difference was noted between the two groups for the primary outcome variables of cleanliness and visibility at any of the five small-bowel segments. Furthermore, no difference was noted for gastric transit time (39.8 min vs 35.7 min;  $P=.63$ ), small-bowel transit time (257.5 min vs 248.6 min;  $P=.59$ ), and the detection of lesions (35.9% vs 42.8%;  $P=.54$ ). The authors concluded that despite the limitations of the study (eg, the use of a nonstandardized, subjective scoring system, and the possibility that too few patients were studied), sodium phosphate prior to capsule endoscopy in patients with gastrointestinal bleeding cannot be recommended based on their results. They acknowledged that further large studies combining preparation and prokinetics with diagnostic yield as the primary endpoint are still necessary.

## Sirolimus for Graft Survival in Orthotopic Liver Transplants

At the recent 2008 American Transplant Congress, held in Toronto, Canada, researchers presented the results of a retrospective review of 1,554 orthotopic liver transplant (OLT) recipients treated at the Baylor Regional Transplant Institute in Dallas/Fort Worth, Texas, between 1998 and 2007 to identify patients who used sirolimus as initial immunosuppression. The remaining OLT patients were used as controls to compare outcomes, complications, and adverse effects. The researchers found that sirolimus was the initial immunosuppressant in 14.9% of OLT patients. Data analysis revealed that, though sirolimus had no impact on patient survival, it significantly increased graft survival, despite a higher prevalence of hepatitis C virus in the sirolimus group. In addition, cytomegalovirus infection was significantly less common and neurotoxicity statistically less common with sirolimus. The researchers concluded that, despite sirolimus-associated cytopenia and hypercholesterolaemia, the adverse effect profile is similar to nonsirolimus-containing regimens and that sirolimus could be used safely as initial immunosuppression in OLT patients with good outcome.