

**Title: A Randomized, Double-blind, Parallel-group Study to Assess the Safety and Efficacy of Asacol® (1.2 to 4.8g/day) 400 mg Delayed-release Tablets Given Twice Daily for 26 Weeks to Children and Adolescents for the Maintenance of Remission of Ulcerative Colitis**

**IRB# 2009-085**

**Principal Investigator: Sabina Ali, MD**

**Synopsis:**

This is a multi-center, multinational, 26-week study of two dose levels of Asacol consisting of a high dose and a low dose in pediatric patients. Randomization will be stratified by weight (17–<33 kg, 33–<54 kg, and 54–90 kg). The high doses in each weight category are approximately 1.67, 1.8 and 2 times the low dose, respectively, keeping within the mg/kg limits of current clinical practice as well as the 400 mg tablet constraint.

Patients will complete visits at Screening, Baseline, Week 6 (phone visit), Week 12, Week 18 (phone visit), and Week 26.

The overall objective of this study is to assess the safety and efficacy of high dose and low dose Asacol given twice daily for 26 weeks for maintaining remission in children and adolescents with ulcerative colitis (UC). The primary efficacy endpoint is the proportion of patients who have maintained complete remission through Week 26 as determined by a PUCAI score < 10 during the entire study period.

The secondary efficacy objective is the proportion of patients who have maintained complete remission through Week 26 using an endpoint similar to the PUCAI (but with the PUCAI 3-level Abdominal Pain question replaced by a 5-level Abdominal Pain question), which is referred to as the Amended Endpoint. Complete remission through Week 26 for the Amended Endpoint is defined as a score of < 10 during the entire study.

Approximately 100 patients will be enrolled with a documented history of UC that has been successfully maintained in remission for at least one month. This study will be conducted globally (United States, Canada, and Europe).