

Summary: A Randomized, Double-Blind, Placebo-Controlled evaluation of the safety, efficacy, and Pharmacokinetics of multiple doses of Basiliximab, with concomitant Corticosteroids, in Steroid-Refractory Ulcerative Colitis.

Inclusion Criteria:

- Male or female subjects, age >18 years and <75 years
- Weight of 40 kg or greater
- Extent of disease must involve at least the left colon (greater than 15 cm beyond the anal verge)
- Moderate to severe disease, defined as a Mayo score of 6 points or greater, including an endoscopic sub score of 2 points or greater
- Concomitant azathioprine or 6-mercaptopurine treatment is permitted during the study if initiated at least 12 weeks before study entry, and if dose has not been changed or stopped for at least 8 weeks before entry
- Concomitant oral aminosalicylate treatment is permitted during the study if initiated at least 4 weeks before study entry, and if the dose has not been changed or stopped during this time

Exclusion Criteria:

- Prior treatment cyclosporine, tacrolimus, methotrexate, or any anti-TNF agent within 3 months before study entry
- If currently taking a nonsteroidal anti-inflammatory agent (NSAID), the inability to discontinue use during study participation
- Intolerance or inability to continue oral corticosteroids during the trial
- Colitis that is indeterminate, suggestive of Crohn's disease, or isolated to the rectum, based on endoscopic and/or biopsy findings
- Severely ill patients as evidenced by greater than 6 episodes of loose stools, all of them bloody, during a 24 hour period
- Chest radiograph abnormalities consistent with an infectious process
- History of malignancy during the previous 5 years or current malignancy, with exception of adequately treated non-melanoma skin cancer or in situ carcinoma of the cervix
- Any ECG abnormalities not approved by the medical monitor
- Treatment with an investigational drug or device within 30 days before entry

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