Call Toll-free 1-800 856-7842 or 828-254-0881 with Extension listed

Name of Study: A Study of the Efficacy and Safety of Etrolizumab Treatment in Maintenance of Disease Remission in Ulcerative Colitis Participants Who Are Naive to Tumor Necrosis Factor (TNF) Inhibitors-LAUREL-(Genentech-Hoffman La Roche)

LINK:

https://clinicaltrials.gov/ct2/show/NCT02165215?term=ulcerative+colitis&recr=Open&state1=NA%3AUS%3ANC&age=12&phase=123&rank=4

PI: William R. Harlan, III, MD

Coordinator: Kelly Roberts x **3427** or Direct-828-350-3027

Summary: This Phase III, double blind, placebo-controlled, multicenter study will investigate the efficacy and safety of etrolizumab in maintenance of remission in patients with moderately to severely active ulcerative colitis (UC) who are naïve to tumor necrosis factor (TNF) inhibitors and refractory to or intolerant of prior immunosuppressant and/or corticosteroid treatment.

Inclusion:

- Diagnosis of UC at least 6 months prior to randomization by endoscopy/histology
- Mod-sev active UC as determined by MAYO score of 6-12 with endoscopic subscore >=2 and rectal bleeding subscore >=1 x days prior ro first dose
- Evidence of continuous UC a min of 20 cm from anal verge (Flex sig/colon)
- Naive to tx with anti-TNF Inhibitors
- Inadequate response/intolerance to azathioprine, 6MP, of MTX
- May be receiving ongoing tx w/ oral ASA's (stable x 4 wks), corticosteroids <30 mg), probiotics, antidiarrheals, azathioprine

Exclusion:

- Prior colonic resection of planned surgery for UC
- Past/present ileostomy/colostomy
- Dx of indeterminate colitis
- Toxic megacolon w/i 12 mos

- Any diagnosis of Crohns
- Past/present fistula or abdominal abscess
- Hx or current colonic mucosal dysplasia
- Patients with known "fixed symptomatic stenosis of the intestine"
- Adenomatous polyps that have been unremoved