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 in Ulcerative Colitis Patients Who Are Refractory to or Intolerant of TNF Inhibitors (HICKORY)-(Genentech-Hoffman La Roche)

LINK:
https://clinicaltrials.gov/ct2/show/NCT02100696?term=ulcerative+colitis&recr=Open&state1=NA%3AUS%3ANC&age=12&phase=123&rank=3

PI: William R. Harlan, III, MD

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

Enrollment Begins: 2015

Enrollment Ends: 2017

Summary: GA28950/28951OLE - "Hickory" & "Cottonwood" studies. "Hickory"- Phase III, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of Etrolizumab compared with placebo during induction and maintenance in patients with moderate to severe active ulcerative colitis who are refractory to or intolerant of anti-TNF inhibitors.

(OLE) Open-label extension "Cottonwood": Safety monitoring of mod-severe UC in patients previously enrolled in parent study.

Inclusion:

- 18-80 years of age, inclusive
- Moderately to severely active UC as determined by the Mayo Clinic Score assessment (MCS)
- Intolerance, loss response or failure to respond to treatment with at least one TNF-inhibitor within the previous 5 years
- Background regimen for UC may include oral 5-ASA, oral corticosteroids, budenoside MMX, probiotics, AZA, 6-MP, or MTX if doses have been stable during the screening period
- Use of highly effective contraception as defined by the protocol

Exclusion:

- A history of or current conditions and diseases affecting the digestive tract, such as indeterminate colitis, Crohn's disease, fistulas or abdominal abscesses, colonic mucosal dysplasia, intestinal obstruction, toxic megacolon, or unremoved adenomatous colonic polyps
- Prior or planned surgery for UC
- Past or present ileostomy or colostomy
- Have received non-permitted inflammatory bowel disease (IBD) therapies (including natalizumab, vedolizumab, and efalizumab) as stated in the protocol
- Chronic hepatitis B or C infection, HIV or tuberculosis (active or latent)