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

Name of Study: **A Study of the Safety and Efficacy of Etrolizumab in Patients with Moderately to Severely Active Crohn's (Bergamot & Juniper Open-Label Extension)- (Genentech-Hoffman-La Roche)**

LINK:
https://clinicaltrials.gov/ct2/show/NCT02394028?term=crohn%27s&recr=Open&state1=NA%3AUS%3ANC&phase=123&rank=4&submit_fld_opt=

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SUMMARY: This is a multicenter, Phase III, double-blind, placebo-controlled study evaluating the safety and efficacy of etrolizumab during induction and maintenance treatment of moderate to severely active Crohn's disease (CD) in patients who are anti-tumor necrosis factor (TNF) naive (TNF-naive) and in patients who are refractory or intolerant of tumor necrosis factor inhibitors.

Inclusion:

- CDAI score of ≥220 to≤480 and PRO score (patient reported outcome) of ≥14 within 7 days prior to randomization, along with presence of active inflammation (SES-CD score of ≥7 or ≥4 in cases of isolated ileitis or post-ileoresection)
- Experienced intolerance, refractory disease, or no response to at least one of the following within 5 years of screening- Immunosuppresants, and/or Anti-TNF therapy
- Diagnosis of CD based on clinical, histopathological, and endoscopic evidence established ≥3 months prior to screening
- Involvement of ileum and/or colon with at least 4 colonic segments traversable by a pediatric scope or 3 segments (colon and/or ileum) for patients who have underone a bowel resection for CD
- Completed a surveillance colon ≤12 months pror to screening if disease of ≥10 yrs duration of ≤5 yrs prior to screening if patient has any rick factors for bowel cancer (may be done during screening)
- Conditions other than CD that might require >20 mg/day of prednisone (or equivalent) during course of study

Exclusion:

- History of alcohol, drug or chemical abuse ≤6 months prior to screening
- Most cancer diagnosis <5 yrs including leukemias, melanomas, renal, Karposi, abnormal cervical smear, high-grade intraepithelial neoplasia grade >1, solid tumors, hematologic malignancies, and CIS
- Hospitalizations (other than elective) ≤4 wks prior to and during screening
- Prior history of active/latent TB or recent suspicious chest x-ray
- Active positive HBV, HCV, HIV
- Organ transplant