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**Name of Study: Safety and Efficacy of GS-5745 in Participants with Moderately to Severely Active Crohn's Disease (Gilead Sciences)**

**LINK:** <https://clinicaltrials.gov/ct2/show/NCT02405442?term=gilead+crohn&rank=1>

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**Summary:** Phase 2, Double-Blind, Randomized, Placebo-Controlled, Multicenter Study Evaluating the Safety and Efficacy of GS-5745 in Subjects with Mod-Severe active CD.

**Enrollment Starts:** July 2015

**Enrollment Ends:** 52 weeks + 3 year extension rollover

**Inclusion:**

1. Age 18-75 who have a documented diagnosis of CD with a minimum disease duration of 6 months with involvement of the ileum and/or colon at a minimum.
2. Moderately-Severely active Crohn's defined by a CDAI total score between 220-450 (inclusive) AND with:
  - PRO2 Score  $\geq 11$ , AND
  - Evidence of active disease as measured by SES-CD:
    - Total score  $\geq 6$ , OR
    - Ulcer presence and size score of 2 or 3, OR
    - If disease is limited to the ileum and/or right colon, a combined score  $\geq 4$  in these two segments
  - Within the previous 5 years, demonstrated an inadequate clinical response, loss of response to, or intolerance of at least one of the following agents;
    - Corticosteroids
      - Persistently active disease despite a hx of at least one 4-wk induction regimen of a dose equivalent to prednisone 30 mg qD x 2 wks of IV for 1 wk, OR
      - Two failed attempts to taper steroids below a dose equivalent of 10 mg qD prednisone, OR

- HX of steroid intolerance
- Immunomodulators
  - Persistently active disease despite a hx of at least one 8-wk regimen of oral azathioprine ( $\geq 1.5$  mg/kg) or 6-MP ( $\geq 0.75$  mg/kg) or intramuscular or SQ MTX ( $\geq 15$  mg) OR
  - HX of intolerance to at least one immunomodulator
- TNF $\alpha$  Antagonists
  - Persistent disease despite a hx of at least one 4-8 wk induction regimen OR
  - Recurrence of symptoms during maintenance therapy with TNF $\alpha$ , OR
  - HX of intolerance to any TNF $\alpha$  agents
- Vedolizumab
  - Persistent disease despite a hx of at least one 4-8 wk induction regimen, OR
  - Recurrence of symptoms during maintenance therapy, OR hx. of intolerance

**Exclusions:**

1. Evidence of abscess at screening
2. Extensive colon resection (subtotal or total colectomy) or Hx of >2 small bowel resections
3. Ileostomy, colostomy, or symptomatic stenosis of the intestine
4. Current use of oral corticosteroids at a dose equivalent to >30 mg/day of prednisone
5. UC or indeterminate colitis
6. Short bowel syndrome
7. Positive stool for C.diff, E. coli, Salmonella, Shigella, Camphylobacter, or Yersinia
8. Treatment with any of the "mabs" or any other monoclonal antibody within 4 wks of screening