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

Name of Study: Efficacy and Safety Study of Mongersen (GED-0301) for the Treatment of Subjects With Active Crohn's Disease (Celgene)

LINK: https://clinicaltrials.gov/ct2/show/NCT02596893?term=Celgene+Crohn%27s+GED&rank=1

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Summary: GED-0301-CD-002: A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study To Investigate the Efficacy and Safety of Mongerson (GED-0301) For the Treatment of Subjects With Active Crohn's Disease.

Enrollment Starts: 3Q2016 x 52 weeks

Enrollment Ends: Treatment ends after 52 wks with rollover into long-term extension-TBD

Inclusion:

- Diagnosis of CD with a duration of at least 3 months prior to the Screening Visit.
- Diagnosis of ileitis, ileocolitis or colitis, as determined by endoscopic, radiographic or any other imaging modality (i.e.,MRI, CT scan)
- Active disease, defined as a CDAI score ≥ 220 and ≤ 450 at screening
- Subject must have a 7-day average stool frequency ≥ 3.5 or abdominal pain ≥ 1.5 at screening.
- Subject must have a total SES-CD ≥ 6 at screening, or the ileum segmental SES-CD ≥ 4 at screening

Must have failed or experienced intolerance to at least one of the following:

  - aminosalicylates; budesonide; systemic corticosteroids; immunosuppressants (ie, azathioprine [AZA], 6-mercaptopurine [6-MP], or methotrexate [MTX]); or biologics

Exclusion:

- Diagnosis of ulcerative colitis (UC), indeterminate colitis, ischemic colitis, microscopic colitis, radiation colitis or diverticular disease-associated colitis
- Subject has local manifestations of CD such as strictures, abscesses, short bowel syndrome; or other disease complications for which surgery might be indicated or could confound the evaluation of efficacy

- Subject had any intestinal resection within 6 months or any intra-abdominal surgery within 3 months prior to the Screening Visit
- Subject had prior treatment with mycophenolic acid, tacrolimus, sirolimus, cyclosporine, thalidomide or apheresis (eg, Adacolumn®) within 8 weeks prior to the Screening Visit
- Use of intravenous (IV) corticosteroids within 2 weeks prior to the Screening Visit
- Use of topical treatment such as 5-aminosalicylic acid (5-ASA) or corticosteroid enemas or suppositories within 2 weeks prior to the Screening Visit
- Use of cholestyramine within 3 weeks prior to the Screening Visit
- Prior treatment with more than 3 biologics for the treatment of CD
- Treatment with a biologic within 8 weeks prior to the Screening Visit