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Name of Study: **Safety and Efficacy Trial of RPC1063 for Moderate to Severe Ulcerative Colitis (Receptos/Celgene)**

LINK:

[https://clinicaltrials.gov/ct2/show/NCT02435992?term=Receptos+Celgene+UC+true+North&rank=1&submit_fld_opt](https://clinicaltrials.gov/ct2/show/NCT02435992?term=Receptos+Celgene+UC+true+North&rank=1&submit_fld_opt=)
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Enrollment Begins: June 2015

Enrollment Ends: 2017

SUMMARY: A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Oral RPC1063 as Induction and Maintenance Therapy for Moderate to Severe Ulcerative Colitis

Main Inclusion Criteria:

- Male or female patients aged 18 to 75 years (at screening), inclusive
- Have had UC diagnosed at least 3 months prior to first investigational drug administration by clinical and endoscopic evidence and corroborated by a histopathology report (note: histopathology may be performed at Screening if no prior report is readily available)
- Evidence of UC extending ≥ 15 cm from the anal verge as determined by Baseline endoscopy (flexible sigmoidoscopy or colonoscopy)
- Have active UC defined as Mayo score of 6 to 12 inclusive, with endoscopic subscore of ≥ 2 , a rectal bleeding score of ≥ 1 , and a stool frequency score ≥ 1
- Must be currently receiving treatment with at least 1 of the following therapies and must continue on these therapies during Induction:
 - Oral aminosalicylates at a therapeutic dose for their disease (eg, mesalamine, sulfasalazine, olsalazine, balsalazide), with the dose stable for at least 3 weeks, prior to Screening endoscopy
 - Prednisone (doses ≤ 20 mg per day) or equivalent receiving a stable dose for at least 2 weeks
 - Budesonide MMX therapy receiving a stable dose for at least 2 weeks

- Have undergone colonoscopy or sigmoidoscopy within the past 2 years or as recommended by local and national guidelines or willing to undergo a colonoscopy in lieu of a flexible sigmoidoscopy at Screening. This colonoscopy must:
 - Confirm disease extent, defined as 1) left-sided colitis (up to the splenic flexure), 2) extensive colitis (beyond the splenic flexure but not involving the entire colon), and 3) pancolitis
 - Include removal of any adenomatous polyps prior to trial entry
 - Document evidence of surveillance for dysplasia for all patients with left-sided colitis of > 12 years duration and total /extensive colitis of > 8 years duration
- If oral aminosalicylates or corticosteroids have been recently discontinued, they must have been stopped for at least 2 weeks prior to the endoscopy used for Baseline Mayo Score
- Males and females of childbearing potential must agree to use adequate birth control measures during the trial. Acceptable methods of birth control in this trial include: surgical sterilization, intrauterine device, oral contraceptive, contraceptive patch, long-acting injectable contraceptive, partner's vasectomy, double-barrier method (condom or diaphragm with spermicide or condom with diaphragm), or abstinence during trial participation and for 30 days after their last dose of investigational drug. Sites must use the most stringent form of birth control as specified by local regulations, including directions from ethics committees and regulatory bodies if provided.
- Ability to provide written informed consent and to be compliant with the schedule of protocol assessments
- Patients must have documentation of positive Varicella zoster virus (VZV) immunoglobulin G (IgG) antibody status or complete VZV vaccination at least 30 days prior to randomization

Main Exclusion Criteria:

- Have severe extensive colitis as evidenced by:
 - Physician judgment that the patient is likely to require colectomy or ileostomy within 12 weeks of Baseline
 - Current or recent (within 3 months) evidence of fulminant colitis, toxic megacolon, or bowel perforation
 - Diagnosis of Crohn's disease or indeterminate colitis or the presence or history of a fistula consistent with Crohn's disease or microscopic colitis or radiation colitis or ischemic colitis
- Have positive stool examination for pathogens (ova and parasites, bacteria) or positive test for *Clostridium difficile* (*C. difficile*) at Screening. Patients may be treated and retested but must have negative stool culture for pathogens [ova and parasites, bacteria] within 30 days of Day 1 (Induction Period) and 60 days of Day 1 (Induction Period) for *C. difficile*.
- Pregnancy, lactation, or a positive serum β -human chorionic gonadotropin (β -hCG) measured during Screening
- Clinically relevant hepatic, neurological, pulmonary, ophthalmological, endocrine, psychiatric, or other major systemic disease making implementation of the protocol or interpretation of the trial difficult or that would put the patient at risk by participating in the trial
- Clinically relevant cardiovascular conditions, including history or presence of:
- Recent (within the last 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, Class III/IV heart failure, sick sinus syndrome, or severe untreated sleep apnea

- Prolonged Fridericia's corrected QT interval (QTcF; QTcF > 450 msec for males, > 470 msec for females), or at additional risk for QT interval prolongation (eg, hypokalemia, hypomagnesemia, congenital long-QT syndrome, concurrent therapy with QT prolonging drugs)
- Resting HR < 55 bpm when taking vital signs as part of a physical exam at Screening
- History of diabetes mellitus type 1, or uncontrolled diabetes mellitus type 2 with glycosylated Hb (HbA1c) > 9% , or diabetic patients with significant comorbid conditions such as retinopathy or nephropathy
- History of uveitis macular edema
- Known active bacterial, viral, fungal, mycobacterial infection, or other infection (including tuberculosis [TB] or atypical mycobacterial disease [but excluding fungal infection of nail beds, minor upper respiratory tract infections and minor skin infections]) or any major episode of infection that required hospitalization or treatment with intravenous antibiotics within 30 days of screening or oral antibiotics within 14 days of screening
- History or known presence of recurrent or chronic infection (eg, hepatitis A, B, or C, human immunodeficiency virus (HIV); recurrent urinary tract infections are allowed)
- History of cancer, including solid tumors and hematological malignancies (except basal cell and in situ squamous cell carcinomas of the skin or uterine cervix that have been excised and resolved) or colonic mucosal dysplasia
- History of alcohol or drug abuse within 1 year prior to randomization
- History of or currently active primary or secondary immunodeficiency