The REVOLVE Study

A study to evaluate the efficacy and safety of the orally administered drug Mongersen (GED-0301) for the treatment of active Crohn’s disease.

Study Objective:

The REVOLVE Study is an international clinical research study that will involve more than 1000 patients. It will look at a potential new treatment option for people with active Crohn’s disease.

The potential treatment—an investigational medication—is called Mongersen. It is a medication that has been designed to impact the cells in the bowel. It may help reduce inflammation and restore balance in the gut. The intent of this potential new treatment is to help people whose Crohn’s did not improve after taking at least one other medication for the treatment of Crohn’s.

Summary:

The study has 3 periods and will last up to 15 months:

- **Screening Period**
  *Up to 1 month (1 visit)*
  The study team checks if the study is right for the patient.

- **Treatment Period**
  *About 1 year (14 visits)*
  For 52 weeks, the patient will receive either:
  - the investigational medication, or
  - placebo, or
  - the investigational medication and placebo in alternating periods
  The patient will take 4 pills each day.
  If the patient does not get better by the Week 12 visit, if symptoms get worse, or if the patient completes the whole treatment period, the patient may be able to join another study where he or she is guaranteed to receive the investigational medication.

- **Follow-up period**
  *Up to 1 month (1 visit)*
  The study team will complete final health tests and assessments
Taking part in the study is entirely up to the patient, and he or she can leave the study at any time.

Throughout the study, the patient will be carefully monitored by a team of doctors and nurses. All study medication and study-related healthcare procedure will be provided to the patient at no cost. In addition, reasonable travel expenses may be reimbursed.

Eligible Patient Criteria:

Patients may be eligible if they:

- are 18 years of age or older
- have been diagnosed with Crohn’s for at least 3 months
- have active Crohn’s that did not improve or stay improved after trying at least one Crohn’s therapy, or they had to stop previous Crohn’s therapy because of side effects

A study doctor will need to review medical history and carry out some additional health assessments before deciding if the study is right for a particular patient. These assessments will be completed at the University of Colorado Anschutz Medical Campus.

Site Location:

University of Colorado Anschutz Medical Campus
12631 East 17th Avenue
Aurora, CO 80045

Contact Info:

For questions about the study or to refer a patient, please contact:

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More detailed information about the study can be found here.