THE ASTRO STUDY

An Overview for Healthcare Professionals

The information contained in this download is intended for healthcare providers only. This is not to be used with potential participants.

ABOUT THE ASTRO STUDY

The purpose of the **ASTRO Study** is to evaluate the safety and efficacy of an investigational medication compared with placebo in adults with moderately to severely active ulcerative colitis (UC).

Your patients may be eligible if they meet the following criteria:

- Are at least 18 years old
- Have a documented diagnosis of UC at least 3 months prior to screening (a biopsy report supporting the diagnosis is required)
- Are experiencing moderately to severely active UC, defined as a baseline (Week 0) modified Mayo score of 5 to 9, inclusive, using the Mayo endoscopy subscore obtained during the central review of the screening endoscopy
- Have demonstrated an inadequate response to or intolerance of conventional (i.e, 6-MP, AZA, or corticosteroids) or advanced therapy (i.e, TNFα antagonists, a4b7 integrin antagonist, approved JAK inhibitor, or S1P receptor modulator therapies)
- Have a Mayo rectal bleeding subscore ≥1 at baseline
- Have a screening endoscopy with ≥2 on the endoscopy subscore of the Mayo score

WHAT WILL HAPPEN DURING THE ASTRO STUDY?

- The trial consists of four periods:
  - Screening Period (up to 8 weeks)
  - Main Treatment Period (24 weeks)
  - Extension Treatment Period for participants who are eligible to continue on the trial medication and who wish to continue using it (72 weeks)
  - Follow-Up Period (12 weeks after the last dose of trial medication)
- Total possible trial duration is approximately 112 weeks (2 years and 2 months)
- In the Main Treatment Period:
  - Trial visits will occur every 4 weeks for tests and procedures
  - Eligible participants will be randomized in a 1:1:1 ratio to receive one of two doses of the investigational medication or placebo
  - The investigational medication will only be given subcutaneously
  - Participants will be randomized to one of the following trial groups:
    - Group 1: The investigational medication at one dose for the first three trial visits, followed by a lower dose every 4 weeks
    - Group 2: The investigational medication at one dose for the first three trial visits, followed by a lower dose every 8 weeks
    - Group 3: Placebo every 4 weeks (participants in the placebo group will receive the investigational medication at Week 16 if they meet predefined rescue criteria)
- At Week 24, participants entering the 72-week Extension Treatment Period will continue the same trial medication regimen they were receiving prior to Week 24. Trial visits will occur every 4 weeks, but every other visit may be conducted at home via telehealth for participants who qualify.

There are trial clinics located around the world. Find a location near you by visiting weknowibd.com/current-trials.html.

IF YOU HAVE PATIENTS WITH UC WHO MAY BE CANDIDATES, SPEAK TO THEM ABOUT THE POSSIBILITY OF PARTICIPATING IN THIS TRIAL.

HELP YOUR PATIENTS LEARN MORE ABOUT THE ASTRO STUDY:

844-436-0494

WEKNOWIBD.COM/ABOUT-THE-ASTRO-STUDY.HTML

About Janssen

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. Visit Global Trial Finder to locate Janssen clinical trials that may be looking for participants all around the world.

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