THE GRAVITI 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 **GRAVITI Study**

The purpose of the **GRAVITI Study** is to evaluate the safety and efficacy of an investigational medication compared with placebo in adults with moderately to severely active Crohn's disease.

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

- Are at least 18 years old
- Have been diagnosed with Crohn's disease or fistulizing Crohn's disease at least 3 months prior to screening
- Are experiencing clinically active Crohn's disease defined as a baseline CDAI score ≥220 but ≤450 and either a mean daily SF count ≥4 based on the unweighted CDAI component of the number of liquid or very soft stools OR a mean daily AP score ≥2 based on the unweighted CDAI component of AP
- Have endoscopic evidence of active ileocolonic Crohn's disease, defined as a screening SES-CD score ≥6 (or ≥4 for participants with isolated ileal disease), as assessed by central endoscopy reading
- Prior or current medication for Crohn's disease must include at least 1 of the following:
    - Treatment with oral corticosteroids
    - History of failure to respond to, or tolerate, oral corticosteroids or immunomodulators
    - History of corticosteroid dependence
    - Have previously demonstrated lack of initial response (i.e., primary nonresponders), responded initially but then lost response with continued therapy (i.e., secondary nonresponders), or were intolerant to 1 or more biologic agents at a dose that is at minimum, locally approved for the treatment of Crohn's disease
- Have not previously received a biologic agent targeting IL-12/23 or IL-23

What will happen during the **GRAVITI STUDY?**

- The trial consists of four phases:
  - Screening Phase (up to 5 weeks)
  - Main Treatment Phase (24 weeks)
  - Extension Treatment Phase (72 weeks)
  - Post-Treatment Phase (12 weeks; starts after the last dose of trial medication)
- Participation in the **GRAVITI Study** is expected to last up to 109 weeks (around 2 years)
- Eligible participants will have a 1 in 3 chance of receiving placebo.

  Participants will be randomized into 1 of 3 trial groups as follows:
  - Group 1 – will receive an induction dose at Weeks 0, 4, and 8 followed by a lower-dose regimen of the investigational medication from Week 12
  - Group 2 – will receive an induction dose at Weeks 0, 4, and 8 followed by a higher-dose regimen of the investigational medication from Week 12
  - Group 3 – will receive an induction dose at Weeks 0, 4, and 8 followed by matching placebo from Week 12
- Participants in the placebo group who meet the rescue criteria will be switched to investigational medication at Week 16
- All randomized participants should complete the final follow-up visit approximately 12 weeks after receiving their last dose of trial medication

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 Crohn's disease who may be candidates, speak to them about the possibility of participating in this trial.

Help your patients learn more about the GRAVITI Study:

844-661-2664

weknowibd.com/about-the-graviti-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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