THE DUET-CD 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 DUET-CD STUDY

The purpose of the **DUET-CD Study** is to evaluate the safety and efficacy of a combination of two investigational medications compared to each monotherapy and 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 to 65 years old
- Have been diagnosed with Crohn's disease or fistulizing Crohn's disease with colitis, ileitis, or ileocolitis 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 previously demonstrated an inadequate response or failure to tolerate 1 or more advanced therapies (e.g., infliximab, adalimumab, certolizumab pegol, vedolizumab, or approved biosimilars for these agents)
- Have endoscopic evidence of active ileal and/or colonic Crohn's disease as assessed by a central endoscopy reading at the screening endoscopy

WHAT WILL HAPPEN DURING THE DUET-CD STUDY?

- The trial consists of four periods:


Screening Period (up to 8 weeks)


Induction Dosing Period (12 weeks)


Maintenance Dosing Period (36 weeks)


Follow-Up Period (12 weeks; starts after the last dose of trial medication)

- Eligible participants will be randomized in a 1:2:2:2:2:2 ratio to one of the following trial groups:
    - Group 1: placebo group
    - Group 2: monotherapy group (first investigational medication)
    - Group 3: monotherapy group (second investigational medication)
    - Group 4: combination high-dose group
    - Group 5: combination mid-dose group
    - Group 6: combination low-dose group
- Eligible participants will enter a Long-Term Extension (LTE) Period after the Maintenance Dosing Period, which will be conducted for approximately 4 years (this may include a change of trial medication for participants who did not adequately respond to their initial trial medication)
- Total trial duration is approximately 68 weeks for all participants not enrolled in the LTE, and up to 256 weeks for those enrolled in the LTE
- Participation also includes regularly scheduled trial visits for tests and procedures every 4 weeks

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 DUET-CD STUDY:


844-210-6057


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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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