THE DUET-UC 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-UC STUDY

The purpose of the **DUET-UC 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 ulcerative colitis (UC).

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

- Are at least 18 to 65 years old
- Have been diagnosed with ulcerative colitis at least 3 months prior to screening (a biopsy report supporting the diagnosis is required)
- Are experiencing moderately to severely active ulcerative colitis, defined as a baseline modified Mayo score of 5 to 9, inclusive, using the Mayo endoscopy subscore obtained during the central review of the screening endoscopy
- Have a screening endoscopy with ≥2 on the endoscopy subscore of the Mayo score as obtained during the central review of the endoscopy
- Have demonstrated a lack of initial response, loss of response to, or intolerance to advanced therapy (TNFα antagonist, an IL-12/23 antagonist, α4β7 integrin antagonist, approved JAK inhibitor, or S1P receptor modulator therapies)

WHAT WILL HAPPEN DURING THE DUET-UC 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
- 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 ULCERATIVE COLITIS WHO MAY BE CANDIDATES, SPEAK TO THEM ABOUT THE POSSIBILITY OF PARTICIPATING IN THIS TRIAL.

HELP YOUR PATIENTS LEARN MORE ABOUT THE DUET-UC STUDY:


844-647-0308


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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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