The ANTHEM-UC Research 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 ANTHEM-UC STUDY

The **ANTHEM-UC Study** is a Phase 2, placebo-controlled study to evaluate the efficacy and safety of an oral investigational medication (JNJ-77242113) for the treatment of 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 12 weeks prior to screening, with colitis confirmed at any time in the past by radiography, histology, and/or endoscopy. A biopsy report supporting the diagnosis must be available in the source documentation
- Have moderately to severely active UC, defined as baseline (Week 0) modified Mayo score of 5 to 9 (inclusive)
- Prior or current medication for UC must include at least 1 of the following, and must fulfill additional criteria as applicable:
  - Current treatment with oral corticosteroids (including budesonide and beclomethasone dipropionate) and/or immunomodulators (AZA, 6-MP)

    OR
  - History of failure to respond to, or tolerate, at least 1 of the following therapies: oral corticosteroids (including budesonide and beclomethasone dipropionate) or immunomodulators (AZA, 6-MP)

    OR
  - History of corticosteroid dependence (i.e., an inability to successfully taper corticosteroids without a return of the symptoms of UC)

    OR
  - Has previously demonstrated lack of initial response (primary nonresponse), responded initially but then lost response with continued therapy (secondary nonresponse), or were intolerant to 1 or more advanced therapies at a dose that is, at minimum, a locally approved dose for the treatment of UC (i.e., infliximab, adalimumab, golimumab, vedolizumab, or ustekinumab (or approved biosimilars), approved S1P modulators (i.e., ozanimod), or the approved JAK inhibitors (i.e., tofacitinib, upadacitinib, or filgotinib)

ABOUT THE INVESTIGATIONAL MEDICATION

The IL-23 pathway is a clinically validated pathway in the pathogenesis of IBD (ulcerative colitis and Crohn's disease).

The molecule is designed to bind the IL-23R with high affinity, helping to prevent IL-23 from binding to its receptor. JNJ-77242113 has shown activity in inhibiting IL-23-mediated proximal signaling and downstream effector cytokine productions. The safety and efficacy of JNJ-77242113 in the treatment of IBD have not yet been established.

WHAT WILL HAPPEN DURING THE ANTHEM-UC STUDY?

- The overall study duration is up to 84 weeks and is divided into 4 periods:
  - Screening Period (up to 6 weeks)
  - Main Study (28 weeks)
  - Long-Term Extension (48 weeks)
  - Safety Follow-Up (2 weeks)
- Participants will be randomly assigned to 1 of 4 study groups with a 1:4 chance of receiving placebo. Participants who do not respond to the placebo by Week 16 (based on symptoms, physical exam, labs, and endoscopy results) may be eligible to begin receiving the highest dose of investigational medication.
- Participants will enter a 48-week Long-Term Extension (LTE) after the Main Study ends if they meet clinical response criteria and are expected to benefit from continued treatment with the study medication. This will be determined by the Investigator.
- Participation also includes regularly scheduled study visits for tests and procedures.

There are study 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, PLEASE SPEAK TO THEM ABOUT THE POSSIBILITY OF PARTICIPATING IN THIS STUDY.

Please be sure to include all patients who may qualify via this eligibility criteria. Data has shown that the incidence of IBD is increasing in non-White populations. Diversity in clinical trials is paramount to ensure our medications are safe and effective for all people who may need them.

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

(844) 731-6394

weknowibd.com/about-the-anthem-uc-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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