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A study of JNJ-78934804 in participants with moderately to severely active ulcerative colitis (DUET ENCORE-UC)

Submission date 20/06/2026	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol
Registration date 14/08/2026	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 26/10/2026	**Condition category** Digestive System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Ulcerative colitis (UC) is a chronic disease of the large intestine. Although targeted therapies have improved treatment for UC, many participants do not respond or eventually stop responding to a single therapy, especially after trying multiple treatments. Therefore, exploring new approaches such as combining advanced therapies may help improve outcomes.
JNJ-78934804 is a fixed-dose combination* of guselkumab and golimumab. Guselkumab binds to interleukin-23 (IL-23), and golimumab binds to tumour necrosis factor alpha (TNFα). IL-23 and TNFα normally cause inflammation. By blocking them, this medicine helps reduce the inflammation that occurs in UC.
* Single product containing two drugs in a fixed amount
** Specific types of proteins involved in inflammation
In this study, researchers want to assess how well JNJ-78934804 works compared with guselkumab in participants with UC at Week 48.

Who can participate?
Participants aged 18 years or older with moderately to severely active UC.

What does the study involve?
The study consists of:
1. Screening period (up to 6 weeks)
2. Double-blind treatment period (up to 48 weeks)
2.1. Participants will be randomly assigned to one of the following groups:
2.1.1. JNJ-78934804 group: Participants will receive JNJ-78934804 induction doses administered under the skin at Weeks 0, 4 and 8, followed by maintenance doses every 4 weeks (q4w) from Week 12
2.1.2. Guselkumab group: Participants will receive guselkumab induction doses administered under the skin at Weeks 0, 4 and 8, followed by guselkumab maintenance doses every 4 weeks (q4w) from Week 12
2.2. Participants who meet rescue criteria will receive JNJ-78934804 induction doses at Weeks 16, 20 and 24, followed by JNJ-78934804 maintenance doses every 4 weeks (q4w) from Week 28

3. Long-term extension period (up to 96 weeks)
All randomly assigned and treated participants will complete a safety follow-up visit approximately 12 weeks after their last dose of study intervention.
Safety assessments will include monitoring of adverse events, vital signs, electrocardiograms (tests that record heart activity), clinical laboratory assessments and pregnancy testing.
The overall duration of the study will be approximately 3 years.

What are the possible benefits and risks of participating?
There is no established benefit to participants taking part in this study. Based on scientific theory, JNJ-78934804 may improve ulcerative colitis. However, this cannot be guaranteed because JNJ-78934804 is still being investigated and it is not known whether it will be effective. In addition, participants assigned to the guselkumab treatment group may not receive JNJ-78934804 and may receive only guselkumab during the study, unless otherwise specified.
Participants may experience benefits unrelated to receiving the study drug, such as regular visits and assessments that monitor their overall health. Participation may also help improve treatment for people with UC in the future.
Participants may experience side effects from the study drugs or procedures. These may range from mild to severe and, in some cases, may be life-threatening. Potential risks include:
1. Worsening of UC
2. Serious infections and reactivation of latent infections
3. Hypersensitivity (exaggerated immune response) reactions
4. Malignancy (the presence of cancerous cells that grow in an uncontrolled manner)
5. Congestive heart failure (a condition in which the heart is unable to pump blood efficiently)
6. Demyelinating disorders (conditions that damage the protective myelin sheath surrounding nerve fibres)
7. Lupus-like syndrome (a condition that may be triggered by prolonged use of certain medications, including TNFα inhibitors)
8. Liver injury
9. Haematologic reactions (immune or non-immune responses involving blood products)
Risks associated with study procedures include video endoscopy, which may result in bleeding or intestinal perforation (formation of a hole in the intestine).
There are also other, less frequent risks. The participant information sheet and informed consent form, which all participants must sign before taking part, contain detailed information about the known risks of participation.
Not all possible side effects and risks associated with JNJ-78934804 are currently known. During the study, the sponsor may obtain new information about JNJ-78934804. Participants will be informed as soon as possible of any new information that may affect their decision to continue participating, including any newly identified risks.
To minimise risk, participants will be monitored regularly for side effects and other medical events. Participants will be instructed to report any concerns to the study doctor, who will provide appropriate medical care. Any serious side effects reported to the sponsor will be thoroughly reviewed by a specialist drug safety team.
There is no cost to participants for taking part in the study. The sponsor will pay for the study drug and all study-related tests. Participants will receive reasonable reimbursement for study-related expenses, such as travel and parking costs.

Where is the study run from?
Janssen-Cilag International NV

When is the study starting and how long is it expected to run for?
August 2026 to October 2030

Who is funding the study?
Janssen Research & Development, LLC (USA)

Who is the main contact?
medinfo@its.jnj.com

Contact information

Type(s)
Scientific, Public

Contact name
None - Medical Information and Product Information Enquiry

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Integrated Research Application System (IRAS)
1013939

Central Portfolio Management System (CPMS)
73320

Sponsor's protocol code number
78934804UCO3001

Study information

Scientific Title

A phase 3 randomized, double-blind, and active controlled, multi-center study to evaluate the efficacy and safety of JNJ-78934804 in participants with moderately to severely active ulcerative colitis

Acronym
DUET ENCORE-UC

Study objectives
Primary objective:
To assess how well JNJ-78934804 works when compared to guselkumab at Week 48

Secondary objectives:
1. To assess how well JNJ-78934804 works when compared to guselkumab
2. To assess how safe JNJ-78934804 is compared to guselkumab

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 12/08/2026, Wales REC 5 (Health and Care Research Wales, Floor 4, Crown Building, Cardiff, CF10 3NQ, United Kingdom; no telephone number provided; Wales.REC5@Wales.nhs.uk), ref: 26/WA/0189

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Single

Purpose
Safety

Study type(s)

Health condition(s) or problem(s) studied
Moderately to Severely Active Ulcerative Colitis

Interventions
Experimental: JNJ-78934804
Drug: JNJ-78934804 (guselkumab and golimumab) will be administered subcutaneously. Participants will receive JNJ-78934804 induction dose at Weeks 0, 4, and 8 followed by JNJ-

78934804
maintenance dose, once every 4 weeks (q4w) starting at Week 12. All participants who meet the rescue criteria will receive JNJ-78934804 induction dose at Weeks 16, 20, and 24 followed by JNJ-78934804 maintenance dose q4w starting at Week 28. Participants who complete double-blind (DB) treatment phase (Week 48) and benefit from continued study intervention in the opinion of the
investigator will have the opportunity to enter the long term extension (LTE) phase.

Active Comparator: Guselkumab
Drug: Guselkumab will be administered subcutaneously.
Participants with moderately to severely active UC will receive guselkumab induction dose at Weeks 0, 4, and 8 followed by guselkumab maintenance dose q4w starting at Week 12. All participants who meet the rescue criteria will receive JNJ-78934804 induction dose at Weeks 16, 20, and 24 followed by JNJ-78934804 maintenance dose q4w starting at Week 28. Participants who complete DB treatment phase (Week 48) and benefit from continued study intervention in the opinion of the investigator will have the opportunity to enter the LTE phase.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
JNJ-78934804, Guselkumab

Primary outcome(s)
1. Percentage of Participants in Clinical Remission at Week 48
Clinical remission is defined as an stool frequency (SF) subscore of 0 or 1, rectal bleeding (RB) subscore of 0, and an endoscopy subscore of 0 or 1.

Key secondary outcome(s)
1. Percentage of Participants with Endoscopic Improvement at Week 48
Endoscopic improvement is defined as an endoscopy subscore of 0 or 1.
[Time Frame: At Week 48]
2. Percentage of Participants with Corticosteroid-free (90 day) Clinical Remission at Week 48
Corticosteroid-free (90 day) clinical remission is defined as clinical remission at the visit and not receiving corticosteroids for 90 days prior to the visit.
[Time Frame: At Week 48]
3. Percentage of Participants Achieving a Combination of Histologic Remission and Endoscopic Improvement at Week 48
Endoscopic improvement is defined as an endoscopy subscore of 0 or 1. Histologic remission is defined as an absence of neutrophils from the mucosa (both lamina propria and epithelium), no crypt destruction, and no erosions, ulcerations or granulation tissue according to the Geboes grading system.
[Time Frame: At Week 48]
4. Percentage of Participants with Fatigue Response (PROMIS Fatigue Short Form 7a) at Week 48
Fatigue response is defined as a greater than or equal to (>=) 7-point reduction in the patient-reported outcomes measurement information system (PROMIS) fatigue short form 7a total score from baseline. The PROMIS fatigue SF-7a contains 7 items evaluating fatigue-related symptoms (that is, tiredness, exhaustion, mental tiredness, and lack of energy) and associated

impacts on daily activities (that is, activity limitations related to work, self-care, and exercise).
[Time Frame: At Week 48]
5. Percentage of Participants with Sustained Mayo SF Less Than or Equal to (<=) 1 and RB=0
Percentage of participants with a SF subscore of 0 or 1 and RB subscore of 0 at three assessment time points of Week 12, Week 24, and Week 48 will be reported.
[Time Frame: At Weeks 12, 24, and 48]
6. Percentage of Participants in Abdominal Pain Remission at Week 48
Percentage of participants in abdominal pain remission at week 48 will be reported.
[Time Frame: At Week 48]
7. Percentage of Participants with Inflammatory Bowel Disease Questionnaire (IBDQ) Response at Week 48
IBDQ response is defined as improvement from baseline in the total IBDQ score of >=16 points. The IBDQ is a 32-item, self-reported questionnaire for participants with IBD that will be used to evaluate the disease-specific health-related quality of life (HRQoL) across 4-dimensional scores: bowel symptoms (loose stools, abdominal pain), systemic functions (fatigue, altered sleep pattern), social function (work attendance, need to cancel social events), and emotional function (anger, depression, irritability).
[Time Frame: At Week 48]
8. Percentage of Participants with PROMIS-29 Mental Component Summary (MCS) Response at Week 48
PROMIS 29 MCS response is defined as a >=7-point improvement from baseline in PROMIS 29 MCS response at Week 48. The PROMIS-29 is a collection of short forms containing 4 items for each of 7 domains (depression, anxiety, physical function, pain interference, fatigue, sleep disturbance, and ability to participate in social roles and activities). The PROMIS-29 MCS will be assessed, which is primarily informed by domains of emotional distress (depression/anxiety) and fatigue as well as sleep disturbance where higher MCS scores reflect better mental health.
[Time Frame: At Week 48]
9. Percentage of Participants in Clinical Remission at Week 12
Clinical remission is defined as an SF subscore of 0 or 1, RB subscore of 0, and an endoscopy subscore of 0 or 1.
[Time Frame: At Week 12]
10. Percentage of Participants with Endoscopic Improvement at Week 12
Endoscopic improvement is defined as an endoscopy subscore of 0 or 1.
[Time Frame: At Week 12]
11. Percentage of Participants with Mayo SF/RB Response at Week 2
Mayo SF/RB response is defined as a decrease from baseline in the sum of the SF and the RB subscores by >=30 percent (%) and >=1 point, with either a >=1 point decrease from baseline in the RB subscore or an RB subscore of 0 or 1.
[Time Frame: At Week 2]
12. Percentage of Participants with Adverse Events (AE) and Serious AEs (SAEs)
An AE is any untoward medical occurrence in a clinical study participant administered a pharmaceutical (investigational or non-investigational) product. An AE does not necessarily have a causal relationship with the intervention. An SAE is any untoward medical occurrence that at any dose: results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, is a suspected transmission of any infectious agent via a medicinal product, and is medically important.
[Time Frame: Up to approximately 3 years]

Completion date
16/10/2030

Eligibility

Key inclusion criteria
1. Diagnosis of ulcerative colitis (UC) established at least 12 weeks before screening including both endoscopic evidence and a histopathology report consistent with a diagnosis of UC.
2. Moderately to severely active UC defined as baseline (Week 0) modified Mayo score of 5 to 9, inclusive, using the Mayo endoscopy subscore obtained during central review of the screening video endoscopy
3. An endoscopy subscore >=2 as obtained during central review of the screening video endoscopy
4. Have had an inadequate initial response, loss of response, or intolerance to previous approved systemic therapies

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Isolated proctitis (UC limited to the rectum only or to less than [<] 20 centimeter [cm] from the anal verge) as determined during central review of the screening video endoscopy OR Has a diagnosis of isolated proctitis
2. Diagnosis of indeterminate colitis, microscopic colitis, ischemic colitis, Crohn’s colitis or any findings suggestive of CD
3. Has a history of or ongoing chronic or recurrent infectious disease
4. Has previously demonstrated inadequate initial response, loss of response, allergy, hypersensitivity or intolerance to guselkumab or to golimumab
5. Is a participant who is pregnant, breastfeeding, or planning to become pregnant, or plans to father a child, while enrolled in this study or within 6 months after the last dose of study intervention

Date of first enrolment
28/05/2026

Date of final enrolment
31/07/2027

Locations

Countries of recruitment

United Kingdom

England

Scotland

Wales

Argentina

Australia

Austria

Belgium

Brazil

Bulgaria

Canada

China

Czech Republic

Denmark

France

Germany

Greece

Hungary

India

Israel

Italy

Japan

Korea, South

Malaysia

Mexico

Netherlands

Norway

Poland

Portugal

Romania

Slovakia

Spain

Switzerland

Taiwan

United States of America

Study participating centre
St George's Hospital
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Study participating centre
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Study participating centre
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Sponsor information

Organisation
Janssen-Cilag International N.V.

Funder(s)

Funder type

Funder Name
Janssen-Cilag International N.V

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing policy of Johnson & Johnson Innovative Medicine is available at www.jnj.com /innovativemedicine/our-innovation/clinical-trials/transparency. As noted on this site, requests for access to the study data can be submitted through Yale Open Data Access (YODA) Project site at yoda.yale.edu

IPD sharing plan summary
Available on request