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A long-term extension (LTE) study of guselkumab in pediatric participants

Submission date 02/12/2025	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 03/02/2026	**Overall study status** Ongoing	
Last Edited 26/10/2026	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Ulcerative colitis (UC) is a disease of the large intestine where the lining of the colon (part of the large intestine) becomes inflamed and develops tiny open ulcers. Crohn's disease (CD) is a disease of the digestive system that causes inflammation and ulcers in the intestine. Juvenile psoriatic arthritis (jPsA) is a disease that causes inflammation and pain in the joints along with rashes in children. Guselkumab is a medicine that blocks interleukin-23 (IL-23, specific type of protein involved in inflammation). Blocking the effects of IL-23 helps to reduce the inflammation. This study is to assess the long-term safety of guselkumab in children with moderate-to-severe UC, CD and jPsA.

Who can participate?
Paediatric participants with UC, CD and jPsA who have received benefit from guselkumab therapy during 1 of the 3 primary studies (CNTO1959PUC3001, CNTO1959PBCRD3007, CNTO1275JPA3001) will be provided continued access to it, as per the investigator’s decision.

What does the study involve?
Participants will be assigned to 1 of 2 arms:
1. Guselkumab once every 8 weeks (q8w):
a. Participants from the double-blinded *arm of primary studies (CNTO1959PUC3001 and CNTO1959PBCRD3007) will receive q8w dosing and may get an option to switch to once every 4 weeks (q4w) dosing as per the investigator’s decision. Participants from CNTO1275JPA3001 primary study will continue the same dosing regimen (q8w). Dose changes are not allowed for the q8w arm.
*Neither participants nor the sponsor know which study treatment is given
b. Guselkumab q4w: Participants from the open-label **arm of primary studies (CNTO1959PUC3001 and CNTO1959PBCRD3007) will receive q4w dosing. Participants from CNTO1275JPA3001 primary study will continue the same dosing regimen (q4w). Dose changes are not allowed for the q4w arm.
**Participants and the sponsor both know which study treatment is given
Safety assessments include laboratory tests, physical examinations, vital signs, suicidal thoughts and behaviour monitoring. All side effects will be measured until the study ends (around 7 years).

What are the possible benefits and risks of participating?
There is no established benefit to participants of this study. Based on scientific theory, taking guselkumab may improve UC, CD and jPSA. However, this cannot be guaranteed because guselkumab is still under investigation as a treatment and it is not known whether guselkumab will work. Participants may experience some benefit from participation in the study that is not due to receiving the study drug, but due to regular visits and assessments, monitoring overall health. Participation may help other people with UC, CD and jPSA in the future.

Participants may have side effects from the drugs or procedures used in this study that may be mild to severe and even life-threatening, and they can vary from person to person. The most common, known risks are getting symptoms such as infections of the nose, sinuses, airways, and throat; increased liver enzymes in the blood, headache, joint pain, diarrhoea, and rash. Additional risks include: serious infections, cancer, exaggerated immune response (hypersensitivity) reactions, injection site reactions, and liver injury after getting guselkumab. There are other, less frequent risks. The participant information sheet and informed consent form, which will be signed by every participant agreeing to participate in the study, include a detailed section outlining the known risks of participating in the study. Not all possible side effects and risks related to guselkumab are known at this moment.

During the study, the sponsor may learn new information about guselkumab. The study doctor will tell participants as soon as possible about any new information that might make them change their minds about being in the study, such as new risks. To minimise the risk associated with taking part in the study, participants are frequently reviewed for any side effects and other medical events. Participants are educated to report any such events to their study doctor, who will provide appropriate medical care. Any serious side effects that are reported to the sponsor are thoroughly reviewed by a specialist drug safety team.

There are no costs to participants to be in the study. The sponsor will pay for the study drug and tests that are part of the study. The participant will receive reasonable reimbursement for study-related costs (e.g., travel/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?
October 2024 to December 2031.

Who is funding the study?
Janssen-Cilag International NV

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

Contact information

Type(s)
Scientific, Public

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Clinical Trials Information System (CTIS)
2023-509560-16

Integrated Research Application System (IRAS)
1013158

Protocol serial number
CNTO1959ISD3001

Study information

Scientific Title
A phase 3, multicenter, open-label, basket, long-term extension study to evaluate the safety of guselkumab in pediatric participants with Crohn’s disease, ulcerative colitis, or juvenile psoriatic arthritis

Acronym
TRILOGY

Study objectives
To assess if guselkumab is safe to use over a long period of time in pediatric participants (children) with moderately to severely active ulcerative colitis (UC), or with moderately to severely active Crohn’s disease (CD), or with juvenile psoriatic arthritis (jPsA).

None

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/01/2026, Berkshire Research Ethics Committee (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 0207 104 8156; berkshire.rec@hra.nhs.uk), ref: 25/SC/0403

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Treatment

Study type(s)
Safety

Health condition(s) or problem(s) studied
Moderately to severely active ulcerative colitis (UC), moderately to severely active Crohn's disease (CD), Juvenile psoriatic arthritis (jPsA)

Interventions
Long-term safety study for guselkumab. All patients will receive the active drug, open-label, with no randomisation. The treatment dose will be based on the parent study.

Participants will be assigned to 1 of 2 arms:
1. Guselkumab once every 8 weeks (q8w):
a. Participants from the double-blinded *arm of primary studies (CNTO1959PUC3001 and CNTO1959PBCRD3007) will receive q8w dosing and may get an option to switch to once every 4 weeks (q4w) dosing as per the investigator’s decision. Participants from CNTO1275JPA3001 primary study will continue the same dosing regimen (q8w). Dose changes are not allowed for the q8w arm.
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**Participants and the sponsor both know which study treatment is given
Safety assessments include laboratory tests, physical examinations, vital signs, suicidal thoughts and behaviour monitoring. All side effects will be measured until the study ends (around 7 years).

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Guselkumab

Primary outcome(s)
1. Safety assessments measured using laboratory tests, physical examinations, vital signs, suicidal thoughts and behaviour monitoring at until the study ends (around 7 years)

Key secondary outcome(s)

Completion date
12/12/2031

Eligibility

Key inclusion criteria
1. Must have completed the dosing planned in the primary pediatric guselkumab study.
2. Received benefit from continued guselkumab therapy in the opinion of the investigator.
3. Before enrollment, a participant must be (as defined in Section 10.4) either:
a. Not of childbearing potential, OR
b. Of childbearing potential and not sexually active, practicing abstinence or a highly effective method of contraception (failure rate of <1% per year when used consistently and correctly) and agrees to remain on a highly effective method while receiving study intervention and until 12 weeks after the last dose - the end of relevant systemic exposure. The investigator should evaluate the potential for contraceptive method failure (eg, noncompliance, recently initiated). Examples of highly effective methods of contraception are located in Section 10.4.
4. Participants of childbearing potential must agree not to donate eggs (ova, oocytes) or freeze for future use for the purposes of assisted reproduction during the study and for a minimum of 12 weeks after receiving the last dose of study intervention.
5. During the study and for a minimum of 12 weeks after receiving the last dose of study intervention, a participant capable of producing sperm or ejaculate:
a. who is sexually active with an individual of childbearing potential must agree to use a barrier method of contraception (eg, condom with spermicidal foam/gel/film/cream/suppository)
b. who is sexually active with an individual who is pregnant must use a condom
c. must agree not to donate sperm.
6. Parent(s) (preferably both if available or as per local requirements) or their legally designated representative must sign an ICF indicating that they understand the purpose of, and procedures required for, the study and is/are willing to allow the child to participate in the study. Assent is also required of children capable of understanding the nature of the study (typically 7 years of age and older) as described in Informed Consent Process in Section 10.2.3. An adolescent who signs the assent form will be given the opportunity to sign an adult ICF at a later visit when they reach the age of majority during the study indicating that the participant understands the

purpose of, and procedures required for, the study and is willing to participate in the study.
7. Must be willing and able to adhere to the lifestyle restrictions specified in this protocol, see Section 5.3.

Healthy volunteers allowed
No

Age group
Child

Lower age limit
2 Years

Upper age limit
17 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Is ≥18 years of age and resides in a country where 2 years have elapsed post-marketing authorization for the respective adult indication.
Is <18 years of age and resides in a county where 2 years have elapsed post-marketing authorization for the respective pediatric indication.
2. Are pregnant, nursing, or planning pregnancy or fathering a child.
3. Taken any disallowed therapies as noted in Section 6.9.1, before the planned first LTE dose of study intervention.
4. Employee of the investigator or study site, with direct involvement in the proposed study or other studies under the direction of that investigator or study site, as well as family members of the employees or the investigator.
5. Any condition for which, in the opinion of the investigator, participation would not be in the best interest of the participant (e.g., compromise the well-being) or that could prevent, limit, or confound the protocol-specified assessments.

Date of first enrolment
20/10/2024

Date of final enrolment
05/06/2028

Locations

Countries of recruitment
United Kingdom

Argentina

Australia

Austria

Belgium

Brazil

Canada

China

Denmark

France

Germany

Israel

Italy

Japan

Korea, South

Netherlands

Norway

Poland

Portugal

Spain

United States of America

Study participating centre

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England

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Sponsor information

Organisation
Janssen-Cilag International NV

Funder(s)

Funder type

Funder Name
Janssen-Cilag International NV

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author upon reasonable request. The data sharing policy of the Janssen Pharmaceutical Companies of Johnson and Johnson is available at https://www.janssen.com/clinical-trials/transparency. As noted on this site, requests for access to the study data can be submitted through the Yale Open Data Access (YODA) Project site at yoda.yale.edu.

IPD sharing plan summary
Available on request, Stored in non-publicly available repository