



# A Study of the Efficacy and Safety of Guselkumab in Participants with Moderately to Severely Active Crohn's Disease

21/11/2024 20:19:26

## Main Information

**Primary registry identifying number**

LBCTR2019010167

**Protocol number**

CNT01959CRD3001

**MOH registration number**

2018/2/52806

**Study registered at the country of origin**

Yes

**Study registered at the country of origin: Specify****Type of registration**

Prospective

**Type of registration: Justify**

N/A

**Date of registration in national regulatory agency**

20/12/2018

**Primary sponsor**

Janssen Research & Development, LLC

**Primary sponsor: Country of origin**

USA

**Date of registration in primary registry**

29/02/2024

**Date of registration in national regulatory agency**

20/12/2018

**Public title**

A Study of the Efficacy and Safety of Guselkumab in Participants with Moderately to Severely Active Crohn's Disease

**Acronym**

GALAXI

**Scientific title**

A Phase 2/3, Randomized, Double-blind, Placebo- and Active-controlled, Parallel group, Multicenter Protocol to Evaluate the Efficacy and Safety of Guselkumab in Participants with Moderately to Severely Active Crohn's Disease

**Acronym**

GALAXI

**Brief summary of the study: English**

The purpose of this program is to evaluate the efficacy and safety of guselkumab in participants with Crohn's disease.

**Brief summary of the study: Arabic**

الفرض من هذا البرنامج هو تقييم فاعلية وأمان غوزيلكوماب عند استخدامه لدى مشاركين مصابين بداء كرون نشط من متوسط إلى حاد.

**Health conditions/problem studied: Specify**

Moderately to Severely Active Crohn's Disease

**Interventions: Specify**

Phase 2 Dose-Ranging Study (GALAXI 1)

All participants in the Phase 2 study will be randomized to 1 of 5 treatment groups as described below. Participants will remain on their assigned treatment regimens through the end of the 48-week study, unless otherwise specified.

Group 1: Guselkumab Regimen 1 (1200 mg IV q4w x 3 → 200 mg SC q4w)

Participants will receive guselkumab 1200 mg intravenous (IV) induction every 4 weeks (q4w) from Week 0 through Week 8 (ie, total of 3 IV doses). At Week 12, participants will continue treatment with guselkumab 200 mg subcutaneous (SC) maintenance q4w through Week 44.

Group 2: Guselkumab Regimen 2 (600 mg IV q4w x 3 → 200 mg SC q4w)

Participants will receive guselkumab 600 mg IV induction q4w from Week 0 through Week 8 (ie, total of 3 IV doses). At Week 12, participants will continue treatment with guselkumab 200 mg SC maintenance q4w through Week 44.





Group 3: Guselkumab Regimen 3 (200 mg IV q4w x 3 → 100 mg SC q8w)  
Participants will receive guselkumab 200 mg IV induction q4w from Week 0 through Week 8 (ie, total of 3 IV doses). At Week 16, participants continue treatment with guselkumab 100 mg SC maintenance every 8 weeks (q8w) through Week 40.

Group 4: Active Control, Ustekinumab (~6 mg/kg IV → 90 mg SC q8w)  
Participants will receive a single ustekinumab IV induction dose at Week 0 (weight-based IV doses approximating 6 mg/kg as outlined below). At Week 8, participants will receive ustekinumab SC maintenance (90 mg SC q8w) through Week 40.  
- Ustekinumab 260 mg (weight ≤55 kg)  
- Ustekinumab 390 mg (weight >55 kg and ≤85 kg)  
- Ustekinumab 520 mg (weight >85 kg)

Group 5: Placebo → Placebo or Ustekinumab Crossover  
Participants will receive placebo IV q4w from Week 0 through Week 8 (ie, total of 3 IV doses). At Week 12, participants will continue treatment based on their clinical response status as follows:  
- Placebo responders: Continue placebo treatment q4w from Week 12 through Week 44.  
- Placebo nonresponders: Receive a single ustekinumab IV induction dose at Week 12 (weight-based IV doses approximating 6 mg/kg as outlined above). At Week 20, participants will receive ustekinumab SC maintenance (90 mg SC q8w) through Week 44.

### Phase 3 Dose-Confirming Studies (GALAXI 2 and GALAXI 3)

Based on the Phase 2 data, 2 guselkumab dose regimens (ie, IV induction → SC maintenance) were selected for confirmatory evaluation in Phase 3. Identical dose regimens are to be evaluated in both Phase 3 studies.

Group 1: Guselkumab Regimen 1 (200 mg IV q4w x 3 → 200 mg SC q4w)  
Participants will receive guselkumab 200 mg IV induction q4w from Week 0 through Week 8 (ie, total of 3 IV doses). At Week 12, participants will continue treatment with guselkumab 200 mg SC maintenance q4w through Week 44.

Group 2: Guselkumab Regimen 2 (200 mg IV q4w x 3 → 100 mg SC q8w)  
Participants will receive guselkumab 200 mg IV induction q4w from Week 0 through Week 8 (ie, total of 3 IV doses). At Week 16, participants will continue treatment with guselkumab 100 mg SC maintenance q8w through Week 40.

Group 3: Active Control – Ustekinumab (~6 mg/kg IV → 90 mg SC q8w)  
(Same as in GALAXI 1 above)

Group 4: Placebo → Placebo or Ustekinumab Crossover  
(Same as in GALAXI 1 above)

### Key inclusion and exclusion criteria: Inclusion criteria

#### Inclusion Criteria:

- ≥18 years of age at screening
- CD or fistulizing CD of ≥ 3 months duration (defined as ≥ 12 weeks), with colitis, ileitis, or ileocolitis, confirmed at any time in the past by radiography, histology, and/or endoscopy
- Clinically active CD, defined as a baseline CDAI score ≥220 but ≤450 and either: mean daily SF count >3 or mean daily AP score > 1
- Endoscopic evidence of active ileocolonic CD as assessed by central endoscopy reading at the screening endoscopy, defined as a screening SES-CD score ≥ 6 (or ≥ 4 for participants with isolated ileal disease), based on the presence of ulceration in ≥ 1 of the 5 ileocolonic segments, resulting in the following specified ulceration component scores:
  - A minimum score of 1 for the component of “size of ulcers” and
  - A minimum score of 1 for the component of “ulcerated surface”
- At least 1 of the following:
  - Current treatment with oral corticosteroids and/or immunomodulators (AZA, 6-MP, MTX) or
  - History of failure to respond to or tolerate oral corticosteroids or immunomodulators (AZA, 6-MP, MTX) or
  - History of corticosteroid dependence or
  - Prior primary nonresponse, secondary nonresponse, or intolerance to 1 or more biologic agent with at least the minimum dose approved for the treatment of CD (ie, infliximab, adalimumab, certolizumab pegol, vedolizumab, or approved biosimilars for these agents)
  - A female participant of childbearing potential must have a negative urine pregnancy test result at screening and baseline

### Key inclusion and exclusion criteria: Gender

Both

### Key inclusion and exclusion criteria: Specify gender

### Key inclusion and exclusion criteria: Age minimum

18

### Key inclusion and exclusion criteria: Age maximum

99

### Key inclusion and exclusion criteria: Exclusion criteria

#### Exclusion Criteria:

- Complications of CD, such as symptomatic strictures or stenoses, short gut syndrome, or any other manifestation that might confound ability to assess the effect of treatment
- Current or suspected abscess, unless adequately treated ≥ 3 weeks before baseline
- Any kind of bowel resection within 6 months, or any other intra-abdominal or other major surgery within 12 weeks before baseline
- Draining (ie, functioning) stoma or ostomy
- Positive for an enteric pathogen, including Clostridioides difficile toxin in the previous 4 months



- Any of the following prescribed medications or therapies within the specified period:
  - IV corticosteroids within 3 weeks of baseline
  - Cyclosporine, tacrolimus, sirolimus, or mycophenolate mofetil within 8 weeks of baseline
  - 6-thioguanine within 4 weeks of baseline
  - Biologic agents: anti-TNF therapy (eg, infliximab, etanercept, certolizumab pegol, adalimumab, golimumab) within 8 weeks of baseline; vedolizumab within 12 weeks of baseline; ustekinumab within 16 weeks of baseline; other immunomodulatory biologic agents, including approved and investigational biologic agents, within 12 weeks of baseline or within 5 half-lives of baseline, whichever is longer
  - Any investigational intervention within 4 weeks of baseline or within 5 half-lives of baseline, whichever is longer
  - Nonautologous stem cell therapy (eg, Prochymal), natalizumab, efalizumab, or biologic agents that deplete B- or T-cells (eg, rituximab, alemtuzumab, or visilizumab) received within 12 months of baseline
  - Treatment with apheresis (eg, Adacolumn apheresis) or total parenteral nutrition for Crohn's disease within 3 weeks of baseline
- Has previously received a biologic agent targeting IL-12/23 or IL-23, including but not limited to briakinumab, brazikumab, guselkumab, mirikizumab (formerly LY3074828), and risankizumab

**Type of study**

Interventional

**Type of intervention**

Pharmaceutical

**Type of intervention: Specify type**

N/A

**Trial scope**

Therapy

**Trial scope: Specify scope**

N/A

**Study design: Allocation**

Randomized controlled trial

**Study design: Masking**

Blinded (masking used)

**Study design: Control**

Active

**Study phase**

2 to 3

**Study design: Purpose**

Treatment

**Study design: Specify purpose**

N/A

**Study design: Assignment**

Parallel

**Study design: Specify assignment**

N/A

**IMP has market authorization**

No

**IMP has market authorization: Specify****Name of IMP**

Guselkumab

**Year of authorization****Month of authorization****Type of IMP**

Immunological

**Pharmaceutical class**

interleukin inhibitor

**Therapeutic indication**

Crohn's disease

**Therapeutic benefit**

Change in the Crohn's Disease Activity Index (CDAI) Score

**Study model**

N/A

**Study model: Explain model**

N/A

**Study model: Specify model**

N/A

**Time perspective**

N/A

**Time perspective: Explain time perspective**

N/A

**Time perspective: Specify perspective**

N/A

**Target follow-up duration****Target follow-up duration: Unit****Number of groups/cohorts****Biospecimen retention**

Samples without DNA

**Biospecimen description**

No genetic research will be done on the samples, unless specific consent is provided by signing the Optional Genetic Research ICF.

The results of tests done on the samples are only for scientific research.

The video from the endoscopies will be destroyed after a period of about 15 years from the time of study closure.

Some or all of the samples may also be kept and used for up to 15 years.

The sponsor will ensure that samples are kept secure.

**Target sample size**

28

**Actual enrollment target size**

19

**Date of first enrollment: Type**

Actual

**Date of first enrollment: Date**

31/03/2019

**Date of study closure: Type**

Actual

**Date of study closure: Date**

13/07/2027

**Recruitment status**

Complete

**Recruitment status: Specify****Date of completion****IPD sharing statement plan**

No

**IPD sharing statement description**

to be determined in case applicable

**Additional data URL**

<https://clinicaltrials.gov/ct2/show/NCT03466411?term=CNTO1959CRD3001&rank=1>

**Admin comments****Trial status**

Approved



## Secondary Identifying Numbers

No Numbers

## Sources of Monetary or Material Support

**Name**

Janssen Research & Development, LLC

## Secondary Sponsors

No Sponsors

## Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Aziz Zoghbi	Beirut	Lebanon	01-- 612500 ext2040	zog_Az@mct- cro.com	MCT s.a.r.l (CRO)
Scientific	Janssen Research & Development, LLC	US	United States of America	844-434- 4210	JNJ.CT@sylogen t.com	Janssen (Sponsor)



## Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
American University of Beirut	Dr. Ala Sharara	Gastroenterology	Approved
Hotel Dieu De France	Dr. Cesar Yaghi	Gastroenterology	Approved
Mount Lebanon Hospital	Dr. Mona Hallak	Gastroenterology	Approved
Rafik Hariri University Hospital	Dr. Abdullah Al Omary	Gastroenterology	Approved
Bellevue Medical Center	Dr. Bilal hotayt	Gastroenterology	Approved
Saint George Hospital University Medical Center	Dr. Khalil Bedran	Gastroenterology	Approved
Nini Hospital	Dr. Mahmoud Osman	Gastroenterology	Approved
Ain Wazein Medical Village	Dr. Farid Kerbaj	Gastroenterology	Approved

## Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Mount Lebanon Hospital	16/07/2018	Marie Merheb	marie.merheb@mlh.com.lb	05/957000 extension: 1200
Hotel Dieu de France	03/07/2018	virginia khoury	virginia.elkhoury@usj.edu.lb	01-421 229
Rafic Hariri University Hospital	19/06/2018	Amani Mehtar	amani.mehtar@crurhuh.com	01-843834
Bellevue Medical Center	29/06/2018	Wediane Saoud	wediane.saoud@bmc.com.lb	01-682666 ext 7806
Saint George Hospital University Medical Center	12/04/2022	Sandra Berbari	sberbari@stgeorgehospital.org	01-441000 Ext: 1630
Nini Hospital	04/04/2022	Kamleh Ibrahim	kamleh.ibrahim@hopitalnini.com	06-431400, Ext: 3578
Ain w Zein Medical Village	25/03/2022	Itaf Al Ashkar	itaf.alashkar@gmail.com	05-509001 ext. 2018

## Countries of Recruitment

Name
Lebanon
Australia



Austria
Belarus
Belgium
Bosnia and Herzegovina
Brazil
Canada
China
Colombia
Croatia
Czech Republic
France
Georgia
Germany
Hungary
India
Italy
Japan
Jordan
Republic of Korea
Latvia
Lithuania
The Former Yugoslav Rep of Macedonia
Malaysia
Netherlands
New Zealand
Poland
Portugal



Russian Federation
Saudi Arabia
Republic of Serbia
Slovakia
Spain
Taiwan
Tunisia
Turkey
Ukraine
United Kingdom
United States of America

## Health Conditions or Problems Studied

Condition	Code	Keyword
Crohn's Disease	Crohn s disease, unspecified (K50.9)	Crohn's Disease

## Interventions

Intervention	Description	Keyword
Guselkumab Dose 1	Guselkumab will be administered by IV infusion.	Phase 2 (GALAXI 1): Group 1 (Guselkumab)
Guselkumab Dose 2	Guselkumab will be administered by SC injection.	Phase 2 (GALAXI 1): Group 1 (Guselkumab) Phase 2 (GAL AXI 1): Group 2 (Guselkumab)
Guselkumab Dose 3	Guselkumab will be administered by IV infusion.	Phase 2 (GALAXI 1): Group 2 (Guselkumab)
Guselkumab Dose 4	Guselkumab will be administered by IV infusion.	Phase 2 (GALAXI 1): Group 3 (Guselkumab)
Guselkumab Dose 5	Guselkumab will be by SC injection.	Phase 2 (GALAXI 1): Group 3 (Guselkumab)
Guselkumab	Guselkumab will be administered by IV infusion and SC injection.	Phase 3 (GALAXI 2 and 3): Group 1 and Group 2 (Guselkumab)
Ustekinumab	Ustekinumab will be administered by IV infusion and SC injection.	Phase 2 (GALAXI 1): Group 4 (Ustekinumab) Phase 2 (GALA XI 1): Group 5 (Placebo/Ustekinumab) Phase 3 (GALAXI 2 and 3): Group 3 (Ustekinumab) Phase 3 (GALAXI 2 and 3): Group 4 (Placebo/Ustekinumab)
Placebo	Placebo will be administered as IV infusion.	Phase 2 (GALAXI 1): Group 5 (Placebo/Ustekinumab) Phase 3 (GALAXI 2 and 3): Group 4 (Placebo/Ustekinumab)





## Primary Outcomes

Name	Time Points	Measure
The CDAI score will be assessed by collecting information on 8 different Crohn's disease-related variables, with scores ranging from 0 to approximately 600. A decrease over time indicates improvement in disease activity.	Baseline and Week 12	Phase 2: Change from Baseline in the Crohn's Disease Activity Index (CDAI) Score at Week 12
Clinical remission is defined as CDAI less than (<) 150 points.	Week 12	Phase 3: Clinical Remission at Week 12

## Key Secondary Outcomes

Name	Time Points	Measure
Clinical remission is defined as CDAI score <150.	Week 12	Phase 2: Clinical Remission at Week 12
Clinical response is defined as greater than or equal to (>=) 100-point reduction from baseline in CDAI score or CDAI score <150.	Week 12	Phase 2: Clinical Response at Week 12
PRO-2 remission is defined based on average daily stool frequency (SF) and average daily abdominal pain (AP) score.	Week 12	Phase 2 and Phase 3: Patient-Reported Outcome (PRO)-2 Remission at Week 12
Clinical-biomarker response is defined using clinical response based on the CDAI score and reduction from baseline in C-reactive protein (CRP) or fecal calprotectin.	Week 12	Phase 2: Clinical-Biomarker Response at Week 12
Endoscopic Response is measured by the Simple Endoscopic Score for Crohn's Disease (SES-CD). The SES-CD is based on the evaluation of 4 endoscopic components across 5 ileocolonic segments, with a total score ranging from 0 to 56.	Week 12	Phase 2 and Phase 3: Endoscopic Response at Week 12
Clinical remission is defined as CDAI score <150.	Week 48	Phase 3: Clinical Remission at Week 48
Durable clinical remission is defined as CDAI<150 for most of all visits between Week 12 and Week 48.	Week 48	Phase 3: Durable Clinical Remission at Week 48
Corticosteroid-free clinical remission is defined as CDAI score <150 at Week 48 and not receiving corticosteroids at Week 48.	Week 48	Phase 3: Corticosteroid-Free Clinical Remission at Week 48
PRO-2 remission is defined based on average daily stool frequency (SF) and average daily abdominal pain (AP) score.	Week 48	Phase 3: PRO-2 Remission at Week 48
Fatigue response will be based on the Patient-Reported Outcomes Measurement Information System (PROMIS). Fatigue Short Form 7a contains 7 items that evaluate the severity of fatigue, with higher scores indicating greater fatigue.	Week 12	Phase 3: Fatigue Response at Week 12
Endoscopic response is measured by the Simple Endoscopic Score for Crohn's Disease (SES-CD).	Week 48	Phase 3: Endoscopic Response at Week 48



## Trial Results

**Summary results**

**Study results globally**

**Date of posting of results summaries**

**Date of first journal publication of results**

**Results URL link**

**Baseline characteristics**

**Participant flow**

**Adverse events**

**Outcome measures**

**URL to protocol files**