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

11/09/2025 04:31:34

Main Information

Primary registry identifying number
LBCTR2019010167

Protocol number
CNTO1959CRD3001

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
الغرض 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 of3 IV doses). At Week 12, participants will continue treatment with guselkumab 200 mg SC maintenanceq4w 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 of3 IV doses). At Week 16, participants will continue treatment with guselkumab 100 mg SC maintenanceq8w 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@sylogent.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	smberbari@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