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

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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
28/04/2022

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
Arm Title * Type * Description [*]
Phase 2 (GALAXI 1): Group 1 (Guselkumab) Experimental Participants will receive guselkumab (Dose 1) by intravenous (IV) infusion, followed by guselkumab (Dose 2) by subcutaneous (SC) injection. Participants who are eligible and willing to continue guselkumab may enter the Long-Term Extension (LTE) phase and continue to receive guselkumab.
Phase 2 (GALAXI 1): Group 2 (Guselkumab) Experimental Participants will receive guselkumab (Dose 3) by intravenous (IV) infusion, followed by guselkumab (Dose 2) by subcutaneous (SC)

injection. Participants who are eligible and willing to continue guselkumab may enter the LTE phase and continue to receive guselkumab.
Phase 2 (GALAXI 1): Group 3 (Guselkumab) Experimental Participants will receive guselkumab (Dose 4) by intravenous (IV) infusion, followed by guselkumab (Dose 5) by subcutaneous (SC) injection. Participants who are eligible and willing to continue guselkumab may enter the LTE phase and continue to receive guselkumab.
Phase 2 (GALAXI 1): Group 4 (Ustekinumab)
Active Comparator Participants will receive ustekinumab by intravenous (IV) infusion, followed by subcutaneous (SC) injection. Participants who are eligible and willing to continue ustekinumab may enter the LTE and continue to receive ustekinumab.
Phase 2 (GALAXI 1): Group 5 (Placebo/Ustekinumab)
Experimental Participants will receive placebo administered by intravenous (IV) infusion. At Week 12, non-responders will receive active treatment (Ustekinumab) administered by intravenous (IV) infusion followed by subcaneous (SC) injection. Participants who are eligible and willing to continue placebo/ustekinumab may enter the LTE and continue to receive placebo/ustekinumab.
Phase 3 (GALAXI 2 and 3): Group 1 and Group 2 (Guselkumab)
Experimental Participants will receive guselkumab by intravenous (IV) infusion, followed by guselkumab by subcutaneous (SC) injection. Participants who are eligible and willing to continue guselkumab may enter the LTE phase and continue to receive guselkumab.
Phase 3 (GALAXI 2 and 3): Group 3 (Ustekinumab)
Active Comparator Participants will receive ustekinumab by intravenous (IV) infusion, followed by subcutaneous (SC) injection. Participants who are eligible and willing to continue ustekinumab may enter the LTE phase and continue to receive ustekinumab.
Phase 3 (GALAXI 2 and 3): Group 4 (Placebo/Ustekinumab)
Experimental Participants will receive placebo administered by intravenous (IV) infusion. At Week 12, non-responders will receive active treatment (ustekinumab) administered by intravenous (IV) infusion followed by subcaneous (SC) injection. Participants who are eligible and willing to continue
Intervention Name* Type* Associated Arms Description
Guselkumab Dose 1 Drug Phase 2 (GALAXI 1): Group 1 (Guselkumab)
Guselkumab will be administered by IV infusion.
Guselkumab Dose 2 Drug Phase 2 (GALAXI 1): Group 1 (Guselkumab)
Phase 2 (GAL AXI 1): Group 2 (Guselkumab)
Guselkumab will be administered by SC injection.
Guselkumab Dose 3 Drug Phase 2 (GALAXI 1): Group 2 (Guselkumab)
Guselkumab will be administered by IV infusion.
Guselkumab Dose 4 Drug Phase 2 (GALAXI 1): Group 3

(Guselkumab)
Guselkumab will be
administered by IV
infusion.
Guselkumab Dose 5 Drug Phase 2 (GALAXI 1): Group 3
(Guselkumab)
Guselkumab will be by SC
injection.
Guselkumab Drug Phase 3 (GALAXI 2 and 3):
Group 1 and Group 2
(Guselkumab)
Guselkumab will be
administered by IV
infusion and SC injection.
Ustekinumab Drug 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)
Ustekinumab will be
administered by IV
infusion and SC injection.
Placebo Drug Phase 2 (GALAXI 1): Group 5
(Placebo/Ustekinumab)
Phase 3 (GALAXI 2 and 3):
Group 4 (Placebo/Ustekinumab)
Placebo will be
administered as IV

Key inclusion and exclusion criteria: Inclusion criteria

Inclusion Criteria:
- Have Crohn’s disease (CD) or fistulizing Crohn’s disease of at least 3 months duration (defined as a minimum of 12 weeks), with colitis, ileitis, or ileocolitis, confirmed at any time in the past by radiography, histology, and/or endoscopy
- Have moderate to severe CD as assessed by CDAI, stool frequency (SF), and abdominal pain (AP) scores, and Simple Endoscopic Score for Crohn's Disease (SES-CD)
- Have screening laboratory test results within the protocol specified parameters
- A female participant of childbearing potential must have a negative urine pregnancy test result at screening and baseline
- Demonstrated intolerance or inadequate response to conventional or to biologic therapy for CD

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:
- Current diagnosis of ulcerative colitis or indeterminate colitis
- Has complications of Crohn’s disease, such as symptomatic strictures or stenoses, short gut syndrome, or any other manifestation
- Unstable doses of concomitant Crohn's disease therapy
- Receipt of Crohn's disease approved biologic agents (within 8 weeks prior to Baseline), or any investigational biologic or other agent or procedure within 8 weeks prior to baseline (or within 5 half-lives of baseline, whichever is longer)
- Prior exposure to p40 inhibitors or p19 inhibitors
- Any medical contraindications preventing study participation

Type of study

Interventional

Type of intervention

Type of intervention: Specify type

Pharmaceutical

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
N/A

Target sample size
28

Actual enrollment target size

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
31/05/2024

Recruitment status
Recruiting

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	Jansen	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. Iyad issa	Gastroenterology	Approved
Bellevue Medical Center	Dr. Bilal hotayt	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	Rawan yamout	Rawan.Yamout@crurhuh.com	01-832036
Bellevue Medical Center	29/06/2018	Alain Zogheib	alainzo@hotmail.com	01-421000 ext 2335

Countries of Recruitment

Name
Lebanon

Health Conditions or Problems Studied

Condition	Code	Keyword
Crohn's Disease	2-Propanol (T51.2)	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