An induction study to investigate the efficacy and safety of duvakitug in participants with moderately to severely active Crohn's Disease

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	Sujetos incapaces de otorgar consentimiento	Menores de 18 , Mayores de 64 , Adultos (18-64 años) , Adolescentes (12-17 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	1358
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética	NO

Información

Identificador
2025-521036-11-00 (CTIS)

Cod. Protocolo
EFC18326

Área terapéutica
Enfermedades [C] - Patologías del sistema inmunitario [C20]|

Enfermedad investigada
Immune system disseases

Título Científico
A multicenter, multinational, randomized, double-blind, placebo-controlled Phase 3, induction study to evaluate the efficacy and safety of duvakitug in participants with moderately to severely active Crohns Disease

Justificación

No aportado

Objetivo Principal

Sub-Study 2: To assess the efficacy of duvakitug as induction therapy in participants with moderately to severely active CD compared with placebo.

Variables de Evaluación Primaria

Sub-Study 2: Co-primary endpoints US/FDA: Proportion of participants achieving clinical remission per Crohns Disease Activity Index (CDAI) at Week 12
Sub-Study 2: Co-primary endpoints US/FDA: Proportion of participants achieving endoscopic response (Simple Endoscopic Score for Crohn's Disease [SES-CD]) at Week 12
Sub-Study 2: Co-primary endpoints EU/EMA: Proportion of participants achieving clinical remission per 2-item patient-reported outcome (PRO-2) at Week 12
Sub-Study 2: Co-primary endpoints EU/EMA: Proportion of participants achieving endoscopic response (SES-CD) at Week 12

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Sub-Study 2: To assess the efficacy of duvakitug by multiple measures of disease activity.
Sub-Study 2: To evaluate the safety of duvakitug as induction therapy in participants with moderately to severely active CD compared with placebo.
Sub-Study 2: To evaluate the PK and immunogenicity of duvakitug in participants with moderately to severely active CD.

Variables de Evaluación Secundaria

Sub-Study 2: Proportion of participants achieving CDAI clinical response at Week 12
Sub-study 2: Proportion of participants achieving CDAI clinical response and endoscopic response (SES-CD) at Week 12
Sub-study 2: Proportion of participants achieving endoscopic SES- CD remission at Week 12
Sub-study 2: US/FDA: Proportion of participants achieving clinical remission per PRO-2 at Week 12
Sub-study 2: EU/EMA: Proportion of participants achieving clinical remission per CDAI at Week 12
Sub-study 2: Proportion of participants achieving ulcer-free endoscopy (in the subset of participants with ulcers at baseline) at Week 12
Sub-study 2: Change from baseline in Patient-Reported Outcomes Measurement Information System (PROMIS)-Fatigue Short Form 7a T-score at Week 12

Sub-study 2: Proportion of participants achieving CDAI clinical response at Week 4
Sub-study 2: US/FDA: Proportion of participants achieving corticosteroid free remission (in the subset of participants with corticosteroids at baseline) per CDAI at Week 12
Sub-study 2: EU/EMA: Proportion of participants achieving corticosteroid free remission per PRO-2 (in the subset of participants with corticosteroids at baseline) at Week 12
Sub-study 2: Proportion of participants achieving CDAI clinical remission and endoscopic remission (SES-CD) at Week 12
Sub-study 2: Change from baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) total score at Week 12
Sub-study 2: Proportion of participants with no bowel urgency by Numeric Rating Scale (NRS) at Week 12
Sub-study 2: Proportion of participants with CD-related hospitalizations by Week 12
Sub-study 2: Number of participants with any Treatment Emergent Adverse Events (TEAEs), treatment-emergent adverse event of special interest (TEAESIs), treatment-emergent serious adverse event (TESAEs), and TEAEs leading to permanent study intervention discontinuation
Sub-study 2: Serum concentrations of duvakitug
Sub-study 2: Incidence of treatment-emergent Anti-drug Antibodies (ADA) against duvakitug

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Participants aged 18 and 80 years of age at Screening. Where permitted locally, participants 16 to <18 years of age who meet the definition of Tanner Stage 5 for development Confirmed diagnosis of moderately to severely active Crohns Disease (CD) for at least 3 months prior to baseline Demonstrated inadequate response, have shown loss of response or intolerance to conventional therapies or advanced therapies (ATs)

Criterios de Exclusión

Participants with Ulcerative Colitis (UC) or indeterminate colitis
Participants with two entire missing segments of the: terminal ileum, right colon transverse colon, sigmoid and left colon, and rectum
Prior or current high-grade gastrointestinal (GI) dysplasia
Participants on treatment with but not on stable doses of conventional therapy prior to baseline
Participants receiving prohibited medications or therapies
Participants with previous exposure to anti-TL1A investigational therapy

Calendario

(Última actualización: 03/08/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
27/02/2026	No aportado	28/07/2026	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
No aportado	No aportado	No aportado	No aportado	No aportado

Promotor

Sanofi-Aventis Recherche & Developpement France

82 Avenue Raspail

Contact Person

Clinical Services and operations

8006331610

contact-us@sanofi.com

Monetary support: N/A

Tipo de promotor: Comercial

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Centros

No iniciado (--/--/----)

Clinica Gaias Santiago

Santiago De Compostela

CORUÑA

Digestive

No iniciado (--/--/----)

Complejo Hospitalario Universitario De Ourense

Ourense

OURENSE

Digestive

No iniciado (--/--/----)

Hospital Universitario De Cabuenes

Gijon

ASTURIAS

Digestive

No iniciado (--/--/----)

Hospital Universitario Juan Ramon Jimenez

Huelva

HUELVA

Digestive

No iniciado (--/--/----)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Digestive

Medicamentos

Duvakitug
SOLUTION FOR INJECTION
SUBCUTANEOUS INJECTION

-

Principios Activos: N/A

Experimental

Sin resultados

An induction study to investigate the efficacy and safety of duvakitug in participants with moderately to severely active Crohn's Disease

State	Type of participants	Age Ranges
Recruiting	Incapable subjects of giving consent	Less than 18 , Older than 64 , Adults (18-64 years) , Teens (12-17 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	1358
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics	NO

Information

Identifier
2025-521036-11-00 (CTIS)

Protocol Code
EFC18326

Therapeutic area
Diseases [C] - Immune System Diseases [C20]|

Investigated Disease
Immune system disseases

Scientific Title
A multicenter, multinational, randomized, double-blind, placebo-controlled Phase 3, induction study to evaluate the efficacy and safety of duvakitug in participants with moderately to severely active Crohns Disease

Rationale

Not provided

Main Objective

Sub-Study 2: To assess the efficacy of duvakitug as induction therapy in participants with moderately to severely active CD compared with placebo.

Primary Endpoints

Sub-Study 2: Co-primary endpoints US/FDA: Proportion of participants achieving clinical remission per Crohns Disease Activity Index (CDAI) at Week 12
Sub-Study 2: Co-primary endpoints US/FDA: Proportion of participants achieving endoscopic response (Simple Endoscopic Score for Crohn's Disease [SES-CD]) at Week 12
Sub-Study 2: Co-primary endpoints EU/EMA: Proportion of participants achieving clinical remission per 2-item patient-reported outcome (PRO-2) at Week 12
Sub-Study 2: Co-primary endpoints EU/EMA: Proportion of participants achieving endoscopic response (SES-CD) at Week 12

Temporary moments of secondary assessment

Not provided

Secondary Objective

Sub-Study 2: To assess the efficacy of duvakitug by multiple measures of disease activity.
Sub-Study 2: To evaluate the safety of duvakitug as induction therapy in participants with moderately to severely active CD compared with placebo.
Sub-Study 2: To evaluate the PK and immunogenicity of duvakitug in participants with moderately to severely active CD.

Secondary Endpoints

Sub-Study 2: Proportion of participants achieving CDAI clinical response at Week 12
Sub-study 2: Proportion of participants achieving CDAI clinical response and endoscopic response (SES-CD) at Week 12
Sub-study 2: Proportion of participants achieving endoscopic SES- CD remission at Week 12
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Sub-study 2: Serum concentrations of duvakitug
Sub-study 2: Incidence of treatment-emergent Anti-drug Antibodies (ADA) against duvakitug

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Participants aged 18 and 80 years of age at Screening. Where permitted locally, participants 16 to <18 years of age who meet the definition of Tanner Stage 5 for development Confirmed diagnosis of moderately to severely active Crohns Disease (CD) for at least 3 months prior to baseline Demonstrated inadequate response, have shown loss of response or intolerance to conventional therapies or advanced therapies (ATs)

Exclusion criteria

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Participants receiving prohibited medications or therapies
Participants with previous exposure to anti-TL1A investigational therapy

Calendar

(Last Update: 03/08/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
27/02/2026	Not aported	28/07/2026	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
Not aported	Not aported	Not aported	Not aported	Not aported

Sponsor

Sanofi-Aventis Recherche & Developpement France

82 Avenue Raspail

Contact Person

Clinical Services and operations

8006331610

contact-us@sanofi.com

Monetary support: N/A

Sponsor type: Commercial

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Sites

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Medication

Duvakitug
SOLUTION FOR INJECTION
SUBCUTANEOUS INJECTION

-

Active Principles: N/A

Experimental

No results