Alofisel-4001: Postauthorization Safety Study of the Long-Term Safety and Efficacy of Repeat Administration of Darvadstrocel in Patients With Crohn’s Disease and Complex Perianal Fistula

First published: 07/10/2019

Last updated: 31/10/2025

Study Finalised

Administrative details

EU PAS number

EUPAS31439

Study ID

44182

DARWIN EU® study

No

Study countries

- ☐ Austria
- ☐ Czechia

- [ ] France
- [ ] Germany
- [ ] Israel
- [ ] Spain

Study description

The main aim is to check the long-term side effects of a repeat treatment of darvadstrocel and to see if that treatment improves symptoms of Crohn’s disease and complex perianal fistula.
Participants will attend 8 clinic visits and will receive 1 treatment of darvadstrocel at the third visit. An magnetic resonance imaging (MRI) will be performed several times during the study.

Study status

Finalised

Research institutions and networks

Institutions

Takeda

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Institution

Contact details

Study institution contact

Study Contact Takeda TrialDisclosures@takeda.com

Study contact

TrialDisclosures@takeda.com

Primary lead investigator

Study Contact Takeda

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 22/05/2019

Study start date

Planned: 15/01/2021

Actual: 22/12/2020

Data analysis start date

Planned: 22/05/2025

Date of final study report

Planned: 30/09/2025

Actual: 27/08/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Study protocol

Alofisel-4001-clinical-study-protocol-redact.pdf (2.08 MB)

Alofisel-4001-clinical-study-protocol-redact.pdf (1.39 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Clinical trial

Scope of the study:

Safety study (incl. comparative)

Main study objective:

To evaluate the long-term safety of repeat administration of darvadstrocel in subjects with CD and complex perianal fistula by evaluation of adverse events (AEs), serious adverse events (SAEs), adverse events of special interest (AESIs), and pregnancy.

Study Design

Clinical trial randomisation

Non-randomised clinical trial

Study drug and medical condition

Medicinal product name

ALOFISEL

Study drug International non-proprietary name (INN) or common name

DARVADSTROCEL

Medical condition to be studied

Crohn's disease

Additional medical condition(s)

Complex Perianal Fistula

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

50

Study design details

Outcomes

Primary outcomes of the study are assessments of safety parameters through treatment-emergent adverse events (TEAEs), TE serious AEs, Pregnancy, TEAE of special interests- (Immunogenicity/alloimmune reactions, Hypersensitivity, Transmission of infectious agents, Tumorgenicity (applying to malignant tumors only), Ectopic tissue formation, Medication errors), Secondary outcomes included combined remission, clinical remission, clinical response, relapse and time to relapse, new perianal abscess and Change in scores of discharge and pain items of Perianal Disease Activity Index (PDAI) score after darvadstrocel

repeat administration.

Data analysis plan

Count and percentage of participants with AEs, SAEs and AESIs will be summarized by system organ class and preferred term using MedDRA terminology for the overall study population and for relevant subgroups.
All efficacy outcomes will be summarized by visit, as applicable. Proportion of participants with each of following outcomes, along with 95% 2-sided confidence intervals will be provided by visit:1) Clinical remission, 2) Clinical response,3) Combined remission,4) Reopening of any of the treated external openings with active drainage,5) New perianal abscess in treated fistula. In addition, at Weeks 24, 52, 104, and 156, the proportion of participants who changed in status since the previous assessment will be provided. Change from baseline in PDAI discharge and pain subscores will be summarized descriptively by visit. Among participants who achieve combined probability of relapse across time will be estimated using Kaplan-Meier estimator.

Documents

Study report

Alofisel-4001-clinical-study-report-redact.pdf (822.35 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency

but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No