Retrospective observational study on the effect of vedolizumab treatment on patients with inflammatory bowel disease and extraintestinal manifestations. The EMOTIVE study

First published: 11/10/2018

Last updated: 23/04/2024





## Administrative details

EU PAS number	
EUPAS25761	
Study ID	
-	
47153	
DARWIN EU® study	
No	
Study countries	
<del>-</del>	
Beigium	
Denmark	
Study countries  Belgium	

lsı	rael	
Ne	etherlands	
Sv	witzerland	

## Study description

This is retrospective multi-national, multi-centre medical chart review study of patients with inflammatory bowel disease (IBD) and extraintestinal manifestations (EIMs) who have initiated treatment with vedolizumab between 01 January 2015 and 31 December 2016. The study will review the medical charts of patients who have initiated the medical treatment with vedolizumab during the defined eligibility period under standard clinical practice to provide the real-world evidence of treatment effectiveness and safety in the adult patients with ulcerative colitis (UC) or Crohn's disease (CD) and EIMs. Patients who will be taking vedolizumab as per the standard clinical practice will be observed in this study. The data for participants will be collected in two main periods: Pre-index event period (from the data of diagnosis of UC or CD until one day prior to the date when vedolizumab treatment was initiated during the eligibility period), and Post-index event period (from the date when vedolizumab treatment was initiated during the eligibility period until the death of participants, lost-to-follow up, or date of chart abstraction initiation). The overall duration of the study will be 14 months.

#### **Study status**

Finalised

Research institutions and networks

**Institutions** 

IQVIA
United Kingdom
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Institution Non-Pharmaceutical company ENCePP partner

Sheba Medical Center, Meir Medical Center, Tel Aviv Medical Center Israel, Asaf Harofeh medical center, Soroka university medical center, Rambam Medical Center Israel. Zentrum für Gastroenterologie und Hepatologie AG, Centre Hospitalier Universitaire Vaudois Switzerland, University Hospital Zurich, University Hospital Basel, Gastroenterologische Praxis Balsiger, Seibold und Partner Switzerland, LUMC Leiden, Zuyderland ziekenhuis Heerlen, ETZ Netherlands, CHC - Saint Joseph, AZ Groeninge Kortrijk, OLVZ Belgium, Bispebjerg Hospital, Hvidvore University Hospital Denmark, Hvidvore University Hospital

## Denmark

## Contact details

## **Study institution contact**

Study Lead trialdisclosures@takeda.com

**Study contact** 

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## **Primary lead investigator**

Stephan Vavricka

**Primary lead investigator** 

# Study timelines

## Date when funding contract was signed

Planned: 23/06/2017

Actual: 23/06/2017

### Study start date

Planned: 01/11/2018

Actual: 08/01/2019

### Data analysis start date

Planned: 31/03/2020

Actual: 15/01/2020

## Date of final study report

Planned: 30/05/2020

Actual: 08/04/2021

## Sources of funding

• Pharmaceutical company and other private sector

## More details on funding

Takeda

# Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

# Methodological aspects

Study type

Study type list

**Study topic:** 

Disease /health condition

Human medicinal product

### Study type:

Non-interventional study

### Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

#### **Data collection methods:**

Secondary use of data

### Main study objective:

The primary objective of this study is to describe the percentage of patients treated with vedolizumab experiencing resolution of EIMs within 6 months post-treatment initiation.

# Study Design

## Non-interventional study design

Other

## Non-interventional study design, other

Retrospective multi-national, multi-centre medical chart review study

## Study drug and medical condition

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

#### Medical condition to be studied

Inflammatory bowel disease
Colitis ulcerative
Crohn's disease

# Population studied

## Short description of the study population

The study population consisted of adult patients with IBD and EIMs who initiated treatment with VDZ during the defined Eligibility Period.

Inclusion Criteria:
Patient eligibility was determined according to the following criteria prior to
entry into the study:
$\ \square$ The patient diagnosed with moderate to severe UC or CD documented on the
medical records
☐ The patient $\geq$ 18 years of age at initiation of VDZ (index date)
☐ The patient presented, at least, one EIM documented on the medical records
at maximum 2 months before VDZ treatment initiation and it had not been
resolved by the time of initiation
$\ \square$ The patient received at least one dose of VDZ following standard practice for
the treatment of IBD, attended at least one visit after induction and follow-up
information was available for at least 6 months after VDZ initiation
☐ The patient, or when applicable, the patient's legally acceptable
representative signed and dated a written, informed consent form and any

required privacy authorisation prior to the initiation of any study procedures, when required as per local regulations

#### **Exclusion Criteria:**

Any patient who met any of the below mentioned criteria did not qualify for entry into the study:

□ Index date occurred as part of an interventional clinical trial or patient participated in an interventional clinical trial during the follow-up period
 □ The patient was diagnosed with indeterminate/an unspecified type of IBD
 □ The patient initiated VDZ treatment as combination therapy with other biological agents

### Age groups

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

## **Special population of interest**

Immunocompromised

### **Estimated number of subjects**

200

## Study design details

#### **Outcomes**

Primary outcome measure includes the demographic and clinical characteristics, percentage of patients with resolution of EIMs 6 month's post-treatment initiation with vedolizumab. The secondary outcome includes clinical effectiveness at 14 weeks post induction, Month 6 and 12 post treatment initiation, change in physician assessment, disappearance of inflammatory lesions, change in level of C-reactive protein and faecal calprotectin, percentage of patients with EIMs resolution at Month 12, persistence rate at Month 12, time to treatment discontinuation, and safety events.

### **Data analysis plan**

Continuous variables will be described with number of patients with valid or missing observations, mean, standard deviation (SD), median, 25 and 75 percentiles (P25 and P75 respectively), minimum and maximum.

## **Documents**

### **Study results**

Vedolizumab-5041 CSR Synopsis BV 06Apr2022\_Redacted Final.pdf (1.48 MB) Vedolizumab-5041-Synopsis-08Apr2021.pdf (668.71 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

The source for all collected data will be the patient's medical records, which include the standard clinical practice in treatment of the patient.

## 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**