# Vedolizumab-5055: Long Term Outcomes of Drug Program for Biological Treatment in Adult Patients With Ulcerative Colitis in Poland (MAZUREK Study)

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### Administrative details

**Study description** 

EU PAS number		
EUPAS32684		
Study ID		
48425		
DARWIN EU® study		
No		
Study countries		
Poland		

This is a multicenter, non-interventional study including retrospective data collection with prospective follow-up. This study will assess outcomes of the treatment introduced in the scope of Drug Program (DP) addressed to adult patients with ulcerative colitis (UC) in Poland after biological treatment caseation describing relapse rate in this cohort in consecutive periods. DP is a reimbursement program authorized by Ministry of Health in this country to grant patients access to highly specialized therapies, e.g. biologics, such as VDZ. The study is based on data collection from all patients enrolled to treatment in DP between January 2019 and July 2019. The study will have two cohorts based on the treatment received: Infliximab and vedolizumab. The Investigators will invite eligible patients for Visit 1 for data collection (Week 26 after last dose in DP). Retrospective data will be collected from medical charts of the patients who did not complete the treatment and agreed to participate in the study on Visit 1. Prospective follow-ups will be conducted only for patients who completed treatment in DP with response or remission. Prospective followups with patients will be conducted through patient's interview and data will be collected using electronic case report forms (eCRFs) on remote Visit 2 (Week 52 after last dose in DP), Visit 3 (Week 78 after last dose in DP), and Visit 4 (Week 104 after last dose in DP). It is planned that 70 patients who completed DP with response/remission will be prospectively followed-up in MAZUREK study, however, total number of enrolled patients will be higher due to fact that data will also be collected from patients who lost response before treatment completion in the DP. The overall duration to collect the data in this study is approximately 2 years and 2 months.

#### **Study status**

Finalised

### Research institutions and networks

### **Institutions**

### Takeda

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Institution

### Contact details

#### **Study institution contact**

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#### **Primary lead investigator**

Halina Cichoż-Lach

**Primary lead investigator** 

## Study timelines

Date when funding contract was signed

Planned: 23/10/2019 Actual: 23/10/2019

Study start date

Planned: 07/02/2020

Actual: 02/03/2020

#### **Date of final study report**

Planned: 31/10/2024

Actual: 26/09/2024

## Sources of funding

• Pharmaceutical company and other private sector

### More details on funding

Takeda

## Study protocol

Vedolizumab-5055-clinical-study-protocol-redact.pdf (1.49 MB)

## 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:**

Human medicinal product

#### Study type:

Non-interventional study

#### Scope of the study:

Disease epidemiology

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

#### Main study objective:

The primary objective of the study is to assess relapse rate in patients who completed DP with response or remission for UC within Week 26 after biological treatment cessation with infliximab or vedolizumab.

## Study Design

#### Non-interventional study design

Cohort

## Study drug and medical condition

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

#### **Anatomical Therapeutic Chemical (ATC) code**

(L04AA33) vedolizumab

#### Medical condition to be studied

Colitis ulcerative

### 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**

70

## Study design details

#### **Outcomes**

The primary outcome will assess relapse rate after 26 weeks of treatment cessation understood as: any colectomy due to UC, any hospitalization, new course of biological treatment, new course of steroids, necessity to increase a dose of steroids, and new course of an immunomodulator (IMM) (such as azathioprine, 6-mercaptopurine, methotrexate, ciclosporin or tofacitinib) due to exacerbation of UC. Relapse rate in patients who completed DP with response/remission for UC with response within Weeks 52, 78, 104 after treatment cessation with infliximab/vedolizumab, necessity for steroid and biological treatment within Weeks 26, 52, 78, and 104, effectiveness in

induction and maintenance therapy, use of steroids/IMM and real life safety biological treatment in patients with UC in DP.

#### Data analysis plan

Standard descriptive statistic methods will be used which comprise the number of patients, arithmetic mean, standard deviation, minimum, median and maximum. For categorical variables tables of frequencies (absolute and relative frequencies) will be presented. Relapse rates and response rates will be presented with 95 percent (%) confidence intervals. For exploratory analyses of factors influencing response and remission durability groups of patients with relapse reported on each follow-up visit will be compared. In addition, mixed effects models will be performed taking these factors into consideration. The safety endpoints will be presented as incidence rate calculated using persontime analyses.

### **Documents**

#### Study results

Vedolizumab-5055-clinical-study-report-redact.pdf (1.76 MB)

## 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

Other	
Data sources (types), other	
Data will be collected from patients' medical record	ls using e-CRF.
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