Kesimpta long-term retrospective safety study utilizing real- world data from existing multiple sclerosis registries and databases from multiple countries

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## Administrative details

EU PAS number	
EUPAS104255	
Study ID	
104256	
DARWIN EU® study	
No	
Study countries	
Denmark	
France	
Italy	

Sweden

#### **Study description**

This study will research if Kesimpta initiation at any time, dose and/or duration during a multiple sclerosis (MS) patient's treatment journey is associated with an increased risk of malignancy and infections compared to other disease modifying therapies (DMTs) initiation.

#### **Study status**

Ongoing

## Research institutions and networks

## **Institutions**

## **Novartis Pharmaceuticals**

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Institution

## Contact details

## **Study institution contact**

Novartis Clinical Disclosure Officer Trialandresults.registries@novartis.com

Study contact

#### Trialandresults.registries@novartis.com

## **Primary lead investigator**

#### Novartis Clinical Disclosure Officer

**Primary lead investigator** 

## Study timelines

#### Date when funding contract was signed

Planned: 14/04/2021

Actual: 03/03/2022

#### **Study start date**

Actual: 17/03/2023

#### Data analysis start date

Planned: 30/07/2032

#### Date of final study report

Planned: 30/07/2033

## Sources of funding

• Pharmaceutical company and other private sector

## More details on funding

Novartis Pharma AG

## Study protocol

OMB157G2406 Kesimpta Long Term Safety study protocol v1.0\_Redacted.pdf (1.94 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)

# Other study registration identification numbers and links

COMB157G2406

# Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

## Scope of the study:

Safety study (incl. comparative)

#### Main study objective:

In patients diagnosed with MS, to compare the risk of

- 1) malignancy (except non melanoma skin cancers NMSC overall and for predefined type) and
- 2) late-onset infections between Kesimpta-initiators and other DMT-initiators irrespective of therapy discontinuation or switch and
- 3) acute-onset and opportunistic infections between Kesimpta-initiators and other DMT-initiators while on therapy.

# Study Design

#### Non-interventional study design

Other

#### Non-interventional study design, other

Observational, comparative, retrospective, new user cohort study using longitudinal secondary data from national and multi-national real-world databases

# Study drug and medical condition

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

#### Medical condition to be studied

Multiple sclerosis

# 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**

5000

# Study design details

#### **Outcomes**

malignancies (excluding NMSC), pre-defined malignancies, late and acute-onset infections (overall, by type and seriousness) including opportunistic infections. serious adverse events (SAE) (overall, by type, if feasible), suicidal ideation, intestinal or bowel obstruction and sarcoidosis (if feasible)

#### **Data analysis plan**

Analyses will be performed in two stages.

First, data will be analyzed locally for each data source following a common statistical methodology.

Second, the aggregated data or stratified summaries, as appropriate, from each data source will be provided to CRO to conduct integrated analyses using meta-analytical methods.

Annual update reports will be descriptive.

Final and interim reports will include both descriptive and comparative analyses.

In each data source, the Kesimpta-initiator and other DMT-initiator cohorts will

be extracted and described in terms of patient demographics, potential confounders for malignancy and infections, drug use and duration of follow-up. In addition, for each study outcome of interest, the total number of incident and recurrent events, cumulative person time and unadjusted incidence and event rates with 95% confidence intervals (CIs) will be presented.

## 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 source(s), other

MSBase Australia

#### **Data sources (types)**

Disease registry

# Use of a Common Data Model (CDM)

#### **CDM** mapping

No

# Data quality specifications

## **Check stability**

**Check conformance** 

Unknown

## **Check logical consistency**

Unknown

# Data characterisation

#### **Data characterisation conducted**

No