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

First published: 22/05/2023

Last updated: 19/02/2025

Study Ongoing

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

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Novartis Clinical Disclosure Officer

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Study contact

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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 pre-defined 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 conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No