An Observational Study of Ocrelizumab Treated Patients with Multiple Sclerosis to Determine the Incidence and Mortality Rates of Breast Cancer and All Malignancies (VERISMO Study)

First published: 31/07/2019

Last updated: 08/05/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS30752

Study ID

49480

DARWIN EU® study

No

Study countries

Germany

United States

Study description

This is a prospective, non-interventional, longitudinal, observational study of multiple sclerosis (MS) patients who have newly initiated treatment with ocrelizumab.

Approximately 4000 patients (1000 patients from the United States and 3000 patients from Germany) who have initiated treatment with ocrelizumab no more than 30 days prior to study entry, will be followed for a minimum of 6.5 years following their first exposure to ocrelizumab or until death, whichever comes first.

An internal comparator of 1133 patients newly treated with approved MS disease modifying therapies (DMTs) (per local label) other than ocrelizumab (e.g. alemtuzumab, cladribine, dimethyl fumarate, fingolimod, natalizumab, or teriflunomide) will also be enrolled.

Study status

Ongoing

Research institutions and networks

Institutions

F. Hoffmann-La Roche

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Institution

185 centers in Germany and 100 centers in the United States

Contact details

Study institution contact

Erwan Muros global.clinical_trial_registry@roche.com

Study contact

global.clinical_trial_registry@roche.com

Primary lead investigator

Erwan Muros

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 15/05/2018

Study start date

Planned: 17/08/2019

Actual: 27/09/2019

Date of final study report

Planned: 30/11/2030

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

F. Hoffmann-La Roche Ltd

Study protocol

Protocol BA39731 OCREVUS v1_Redacted_final.pdf (1.95 MB)

Protocol-BA39731_OCREVUS_v7_Published_20Apr2026_Redacted.pdf (1.54 MB)

Prot BA39731 ocrelizumab v3, Published Output-1_Redacted.pdf (1.42 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Other study registration identification numbers and links

BA39731

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The research question is to assess and characterize the incidence and mortality rates of breast cancer, all malignancies, and the long-term safety regarding serious adverse events (SAEs) among patients with multiple sclerosis (MS) newly exposed to ocrelizumab under routine clinical care.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

OCREVUS

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

OCRELIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AG08) ocrelizumab

ocrelizumab

Medical condition to be studied

Multiple sclerosis

Population studied

Short description of the study population

Patients with MS from the post-marketing setting who have initiated treatment with ocrelizumab or one of the 6 approved MS DMTs specified in the protocol no more than 30 days prior to study entry will participate in this study.

Patients must meet the following criteria for study entry:

• Signed informed consent

• Have a diagnosis of MS

• Aged 18 years or older

• Newly treated with ocrelizumab (within 30 days before baseline visit [study entry]) according to the local label irrespective of the reason for starting ocrelizumab (ocrelizumab cohort), or

• Newly treated with one of the following 6 approved MS DMTs: alemtuzumab, cladribine, dimethyl fumarate, fingolimod, natalizumab, or teriflunomide (within 30 days before baseline visit [study entry]) according to the local label irrespective of the reason for starting a new MS DMT (internal comparator cohort)

Patients who meet the following criteria will be excluded from study entry:
• Patients who have any prior exposure to rituximab or to any anti CD-20 therapy for MS
• Active participation in interventional clinical trials for MS
• Patients who have received ocrelizumab more than 30 days before baseline visit (study entry)

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Estimated number of subjects

5.133

Study design details

Outcomes

The primary outcome is:
-Incidence rate of breast cancer and all malignancies following the first ocrelizumab treatment among patients with MS
The secondary outcomes include:
-Mortality rate of breast cancer and all malignancies following the first ocrelizumab treatment among patients with MS

-Compare the observed incidence and mortality rates of breast cancer and all malignancies between ocrelizumab-exposed MS patients and MS patients newly treated with one of the 6 approved MS disease modifying therapies (DMTs) specified in the protocol (alemtuzumab, cladribine, dimethyl fumarate, fingolimod, natalizumab, or teriflunomide) as well as general populations
-Event rate of all serious adverse events (SAEs) in the ocrelizumab-treated patients with MS

Data analysis plan

Incidence rates will be calculated as the number of first (i.e. incident) events divided by the total patient-years (PY) at risk. PY at risk will be calculated from the first dose until the event, death, loss to follow-up, study withdrawal, or the end of the study, whichever occurs first. For breast cancer and malignancies an ever-exposed model will be used, irrespective of the exposure duration. For all other SAEs and AESIs, a time-on-drug approach will be used where PYs will be calculated from first dose up to 6 months after the last administration of ocrelizumab. The incidence and mortality rates of breast cancer and all malignancies will be compared with a cohort of patients treated with approved MS DMTs other than ocrelizumab (internal comparator). Comparisons will use time to event regression adjusted for confounding factors. In addition, comparisons include the MSBase Registry and the SEER Program (external comparators).

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

Prospective patient-based data collection

Data sources (types)

Non-interventional study

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