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

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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 who have initiated treatment with ocrelizumab no more than 30 days prior to study entry, will be followed for a minimum of 5 years following their first exposure to ocrelizumab or until death, whichever comes first. An internal comparator of 2,360 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

250 centers Germany, 90 centers United States

Contact details

Study institution contact

David Wormser global.clinical_trial_registry@roche.com

Study contact

global.clinical_trial_registry@roche.com

Primary lead investigator

David Wormser

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: 09/03/2032

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Roche

Study protocol

Protocol BA39731 OCREVUS v1_Redacted_final.pdf(1.95 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)?

Not applicable

Other study registration identification numbers and links

BA39731

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

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

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

OCRELIZUMAB

Medical condition to be studied

Multiple sclerosis

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

5133

Study design details

Outcomes

The primary outcomes are: - Breast cancer - All malignancies, In addition to the primary outcomes, the secondary outcomes include: - Mortality due to breast cancer - Mortality due to all malignancies - All Serious Adverse Events

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, 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 adjused 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 sources (types)

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