Long-Term Surveillance of Ocrelizumab Treated Patients With Multiple Sclerosis (MANUSCRIPT Study)

First published: 28/02/2019

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/31380

EU PAS number

EUPAS28619

Study ID

31380

DARWIN EU® study

No

Study countries

☐ Australia

- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Sweden

Study description

This longitudinal observational study is part of the European Union (E.U.) risk management plan and is designed to further assess the long-term safety profile of ocrelizumab in the real world setting. The study will provide safety data for a 10 year period after ocrelizumab launch, specifically targeting the rate of SAEs, including serious infections and malignancies.

Study status

Ongoing

Research institutions and networks

Institutions

F. Hoffmann-La Roche

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Institution

Contact details

Study institution contact

David Wormser

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: 01/06/2017

Study start date

Planned: 01/08/2019

Actual: 15/07/2019

Data analysis start date

Planned: 14/04/2028

Date of final study report

Planned: 31/01/2029

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

F. Hoffmann-La Roche

Study protocol

Protocol BA39730 ocrelizumab Final v1_approved_Redacted.pdf(1.86 MB)

Prot BA39730 ocrelizumab v1, Published_Redacted.pdf(1.87 MB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Other study registration identification numbers and links

BA39730

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 long-term safety data from theuse of ocrelizumab in patients with MS (overall and by MS type).

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 (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

0

Study design details

Outcomes

The primary objective is to estimate (overall and by MS type) the event rates of serious adverse events (SAEs), including malignancy and serious infections, following ocrelizumab treatment in patients with MS.

Data analysis plan

Data will be analyzed every 6 months.The number of safety events and unadjusted incidence rates with 95% confidence intervals will be provided for each treatment group, ocrelizumab and other DMTs, for each data source. For malignancy and Progressive multifocal leukoencephalopathy (PML), an ever-exposed model will be applied that includes all person-time observed since the first drug dose in the study until censorship. For all other SAEs a time-on-drug approach will be used. For analyses of death, both approaches will be used.Comparison between ocrelizumab and other DMTs, at year 4, 6, 8, and end of the study, will be based on a Cox proportional-hazards regression model adjusted for important covariates and probability of treatment with ocrelizumab.

Data management

Data sources

Data source(s), other

Multiple Sclerosis Documentation System 3D (MSDS3D) Germany, The Big MS Data (BMSD) Group, a collaboration of MS registries, France, Italy, Sweden Denmark, International registry 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