A Study Assessing the U.S. Post-Marketing Safety Profile of Rebif® in comparison with its U.S. Prescribing Information

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Study Finalised

Administrative details

EU PAS number

EUPAS7290

Study ID

49543

DARWIN EU® study

No

Study countries

☐ United States

Study description

Interferon beta-1a 3x/wk subcutaneously IFN β-1a was approved in 2002 by the United States (U.S.) Food and Drug Administration (FDA) for the treatment of patients (pts) with relapsing-remitting (RR) forms of multiple sclerosis (MS) under the brand name of Rebif®. Within the U.S., the FDA, as part of the Sentinel Initiative, is now conducting post-marketing studies utilizing a variety of healthcare databases in order to characterize the real world safety profile of a broad array of drug products. Similarly, the proposed exploratory study seeks to utilize healthcare claims data to examine the real world, post-marketing safety profile of Rebif in regard to its U.S. label. Such real world data on Rebif is valuable for benefit-risk assessment purposes as well as for informational purposes for both internal stakeholders (e.g. medical, commercial, regulatory, health services research, business strategy) and key external stakeholders (e.g., healthcare prescribers, patients, health authorities).

Study status

Finalised

Research institutions and networks

Institutions

Merck Healthcare KGaA

Germany

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Institution

Contact details

Study institution contact

Communication Center Merck KGaA

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Study contact

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Primary lead investigator

Communication Center Merck KGaA

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 03/02/2014

Study start date

Actual: 01/07/2014

Data analysis start date

Actual: 30/07/2014

Date of final study report

Planned: 07/12/2014

Actual: 14/12/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

EMD Serono Inc.

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To characterize the post-marketing safety profile of Rebif with regards to its safety profile as presented in its U.S. label.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

REBIF

Medical condition to be studied

Multiple sclerosis

Population studied

Short description of the study population

Adult subjects with relapsing-remitting forms of multiple sclerosis receiving treatment of Rebif, a drug approved by the US FDA in 2002.

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)

Special population of interest

Other

Special population of interest, other

Multiple Sclerosis patients

Estimated number of subjects

8107

Study design details

Outcomes

Incidence (n, %, per 100,000 patients-year) of specific events as set forth in the April 2014U.S. Prescribing Information for Rebif:1. Warnings & Precautions2. Adverse Drug Reactions3. Postmarketing Experience sections

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Data analysis plan

Events of interest will be described at MedDRA Preferred Term level and further categorized into System Organ Classes. Descriptive analysis will be conducted and incidence rates with 95% confidence intervals per 100 person-years of labeled AEs will be calculated.

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

U.S.Truven MarketScan© Commercial and Medicare Supplemental healthcare claims database United States

Data sources (types)

Administrative healthcare records (e.g., claims)

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