A Study to Evaluate the Effectiveness of the Additional Risk Minimisation Measures (aRMMs) for REBLOZYL Among Healthcare Professionals (HCPs) in the European Economic Area (EEA) (ACE-536-MDS-005)

First published: 15/07/2021

Last updated: 20/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS42016

Study ID

49997

DARWIN EU® study

No

Study countries

Austria

Belgium

Germany

Italy

Study description

This is a non-interventional post-authorization safety study (PASS) employing a cross-sectional design to evaluate the effectiveness of the additional risk minimization measures (aRMMs) for REBLOZYL. A survey will be used to measure the knowledge and comprehension of the REBLOZYL aRMMs among European Economic Area (EEA) based healthcare professionals (HCPs). The PASS will be conducted among HCPs in a representative sample of EEA countries where REBLOZYL is commercially available, potentially including Austria, Germany, Italy, Norway, Sweden, the Netherlands, Poland, and Spain. Additional EEA countries may be included, as needed, based on commercial availability and reimbursement status.

Study status

Finalised

Research institutions and networks

Institutions

Celgene International

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Institution

Contact details

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Primary lead investigator

Samuel Ewusie

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/01/2021

Actual: 18/01/2021

Study start date

Planned: 20/07/2021

Actual: 26/07/2021

Data analysis start date

Planned: 03/11/2022

Actual: 03/11/2022

Date of final study report

Planned: 30/09/2023

Actual: 28/06/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

CELGENE INTERNATIONAL II SARL, a BRISTOL MYERS SQUIBB COMPANY

Study protocol

Protocol_2D_Evaluation_aRMMs_for_REBLOZYL.pdf (471.43 KB)

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)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The overall goal of this PASS is to assess the awareness and knowledge levels of HCPs regarding key messages included in the nationally implemented aRMMs for REBLOZYL. Awareness encompasses receipt of the educational material and any other way HCPs can learn about the risks associated with REBLOZYL.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Survey

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B03XA06) luspatercept

luspatercept

Population studied

Short description of the study population

A survey of healthcare professionals who prescribed REBLOZYL for the treatment of haematological diseases, were a part of additional risk minimisation measures (aRMMs) dissemination list and practiced in any of the participating European economic area (EEA) countries.

Inclusion criteria:

- HCPs experienced in the treatment of haematological diseases who may intend to prescribe REBLOZYL in the participating European countries and were on the target group for dissemination of the aRMMs
- The HCP provides permission to share their responses in aggregate with the European Medicines Agency (EMA) or NCA, if requested

Exclusion criteria:

- HCPs who previously participated in the cognitive pre-testing of the survey questionnaire to be used for the study
- HCPs who have been direct employees of the MAH, the EMA, or the study vendor within the past 5 years

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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

200

Study design details

Outcomes

Knowledge of the key messages included in REBLOZYL HCP Checklist, assessed as the percentages of HCPs with correct responses to each question. Levels of providing WCBP with the REBLOZYL Patient Card, assessed as the percentage of HCPs who report providing REBLOZYL Patient Card “always”, Levels of knowledge for all 5 core questions. Awareness, reading, use of REBLOZYL HCP Checklist, assessed as percentages of HCPs who report awareness, reading, and use of the REBLOZYL HCP Checklist. Distribution of responses regarding the primary source(s) from which HCPs learned about the messages included in the REBLOZYL HCP Checklist, assessed as the percentages of HCPs who report using each of the possible sources as the primary source.

Data analysis plan

The primary analysis population will include all HCPs who met the eligibility criteria and who have completed all items included in the core question set. Knowledge levels for all key messages in the REBLOZYL HCP Checklist will be calculated with 95% 2-sided CI. Knowledge levels will also be stratified by relevant subgroups. The core question set includes 5 questions. For questions included in the core question set, and for the question regarding providing WCBP with the REBLOZYL Patient Card, the percentage of HCPs who answer each core question correctly will be estimated and assessed against the 80% (± 95% CI) target. The success criteria threshold will only be applied when the

number of HCPs who answered a question is at least 30.

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

All data for the actual survey will be collected by web-based data capture.

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