TG1101-RMS402

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000611

Study ID

1000000611

DARWIN EU® study

No

Study countries

☐ Germany

Study description

The overall objective of the study is to characterize the long-term safety of ublituximab in adult patients diagnosed with relapsing multiple sclerosis (RMS) in a post-approval real-world setting.

The primary objective of the study is to estimate the incidence rate of long-term safety events of interest, including total malignancies (including non-melanoma skin cancer [NMSC]), malignancies (excluding NMSC) (delayed-onset) and serious infections (acute-onset), in patients treated with ublituximab for RMS, as compared to RMS patients treated with other approved disease-modifying therapies (DMTs).

The secondary objectives of this study are:
- To estimate the incidence rate of NMSC in patients treated with ublituximab for RMS as compared to RMS patients treated with other approved DMTs.
- To assess the overall safety of ublituximab in patients with RMS as compared to patients with RMS exposed to other approved DMTs

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Study status

Ongoing

Research institutions and networks

Institutions

Neuraxpharm Pharmaceuticals, S.L.

Networks

German MS Society MS Registry

Contact details

Study institution contact

Jackie Parker jackie.parker@tgtxinic.com

Study contact

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Primary lead investigator

Andreas Schmitt

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/03/2023

Actual: 29/01/2025

Study start date

Planned: 18/12/2024

Actual: 18/12/2024

Data analysis start date

Planned: 29/01/2034

Date of interim report, if expected

Planned: 01/01/2034

Date of final study report

Planned: 01/06/2034

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

TG1101-RMS402 _21Aug2024_ Final-Signed.pdf(1.19 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

This will be a multi-registry, multi-centre, long-term, observational study of adult RMS patients (≥18 years) treated with ublituximab or comparator RMS standard of care medication.

Main study objective:

The overall objective of the study is to characterize the long-term safety of ublituximab in adult patients diagnosed with relapsing multiple sclerosis (RMS) in a post-approval real-world setting.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

BRIUMVI

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

UBLITUXIMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AG14) ublituximab

ublituximab

Medical condition to be studied

Relapsing-remitting multiple sclerosis

Population studied

Short description of the study population

Adult patients diagnosed with relapsing multiple sclerosis (RMS)

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

1772

Study design details

Setting

The study population will consist of adult RMS patients (≥18 years) divided into 3 study cohorts for
delayed-onset outcomes and 3 study cohorts for acute-onset outcomes, i.e., patients treated with ublituximab, patients treated with other anti-CD20 treatments, and patients treated with other standard RMS treatments acting through a different mechanism that are approved in the countries participating in the study at the time of patient enrolment.

Comparators

Other DMTs

Outcomes

Total malignancy includes skin cancers, solid cancers, and hematologic cancers. Cases of malignancy will be identified using the Medical Dictionary for Regulatory Activities (MedDRA) Standardised MedDRA query (SMQ) “Malignancy”. Total malignancy events including NMSC (defined in Section 9.3.2.2.1. will be assessed in the primary analysis.

Malignancy excluding NMSC includes solid cancers and hematologic cancers. Cases of
malignancy will be identified using the MedDRA SMQ “Malignancy”. All malignancy events
excluding NMSC (defined in Section 9.3.2.2.1. will be assessed in the primary analysis.

Serious infections include infections requiring or prolonging hospitalisation; life-threatening
infections; infections leading to death; infections causing disability; infections

causing permanent
damage or congenital abnormality; or medically significant infections (e.g., infections requiring
parenteral or intravenous antibiotics). Cases of serious infection will be identified using the
MedDRA System Organ Class (SOC) “Infections and Infestations”. All serious infection events
will be assessed in the primary analysis. Serious infection sub-categories including but may not
be limited to PML (treated as a delayed onset outcome) and hepatitis B reactivation will also be
assessed.

Data analysis plan

Analyses will be conducted separately for each outcome by the GMSR or the respective registry or its
subcontractor and will include descriptive analyses, comparative analyses (where appropriate), and any relevant sensitivity analyses.

Descriptive statistics will include percentages, means with standard deviations, and event incidence rates. Baseline tables will include the number of patients contributing multiple exposure episodes, including those patients who begin in the comparator cohort(s) before contributing to the ublituximab cohort and those patients who only contribute exposure episodes to the comparator cohort(s).

Propensity scores will be calculated for each exposure episode and used to create a common support population and address imbalances in the patient population that may confound the association between treatment and study outcomes.

Inferential statistics include hazard ratios from frailty Cox proportional hazard models and a two-sided type I error rate of 0.05 will be used. Including the

frailty term in the Cox model accounts for the possibility of multiple exposure episodes per patient per cohort when the PS model is applied to the exposure-level dataset.
The proportional hazards assumption will be evaluated prior to fitting the Cox model. Details of the
statistical approach are provided in the following sections. For all analyses, ublituximab will be the treatment of interest and the comparator cohort (either other DMT or other anti-CD20 treatments) will be the reference group. Comparisons with patients receiving other anti-CD20s is intended to provide information about the potential risk of secondary outcomes associated with ublituximab that may not be found with a comparison to other DMT medications. The GMSR will conduct its analyses in R Stat (R Core Team 2021).

Data management

Data sources

Data source(s), other

German MS Society MS Registry

Data sources (types)

Drug 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

Unknown