BRIUMVI® Pregnancy Registry: A Prospective Study of Pregnancy and Infant Outcomes in Patients Treated with BRIUMVI®

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Study | Ongoing

Administrative details

EU PAS number

EUPAS1000000614

Study ID

1000000614

DARWIN EU® study

No

Study countries

United States

Study description

The BRIUMVI™ Pregnancy Registry is a prospective, observational cohort study designed to evaluate the association between BRIUMVI™ exposure during pregnancy and subsequent maternal, fetal, and infant outcomes.

The outcomes of interest include major congenital malformations (MCMs; primary outcome), minor congenital malformations, gestational hypertension, pre-eclampsia, eclampsia, gestational diabetes, spontaneous abortions (SAB), stillbirths, elective terminations, small for gestational age (SGA), preterm births, postnatal growth deficiency, infant developmental delays, infant serious or opportunistic infections, and infant hospitalizations.

Study status

Ongoing

Research institutions and networks

Institutions

TG Therapeutics, Inc.

Contact details

Study institution contact

Jackie Parker jackie.parker@tgtxinic.com

Study contact

jackie.parker@tgtxinic.com

Primary lead investigator

Syd Phillips

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 08/09/2023

Actual: 08/09/2023

Study start date
Planned: 31/05/2024

Actual: 31/05/2024

Date of final study report
Planned: 31/03/2035

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

Approved CLIN-PROTOCOL-1069 with External Approver.pdf (2.49 MB)

tg1101-rms403-protocol-v2.0_09Jul2025.pdf (863.38 KB)

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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:

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

The BRIUMVI™ Pregnancy Registry is a US-based, prospective, observational cohort study designed to evaluate the association between BRIUMVI™ exposure during pregnancy and subsequent maternal, fetal, and infant outcomes.

Main study objective:

The primary objective of the BRIUMVI™ Pregnancy Registry is to compare the maternal, fetal, and infant outcomes of pregnant individuals with multiple sclerosis (MS) who are exposed to BRIUMVI™ during pregnancy with outcomes of an internal comparison cohort of pregnant individuals with MS who are not exposed to BRIUMVI™ or other anti-CD20 monoclonal antibodies at any time during pregnancy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

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

The study population will include 2 internal cohorts of pregnant individuals with MS and 1 “external cohort” representing the general population in the US.
The internal study population will include pregnant individuals 15–50 years of age who provide consent to participate in the study, agree to medical releases for their HCPs to provide data to the registry, and meet the criteria for inclusion into 1 of the following cohorts:
- Exposed cohort: Pregnant individuals with MS who are exposed to BRIUMVI™ at any time during pregnancy
- Unexposed cohort: Pregnant individuals with MS who are not exposed to BRIUMVI™ or other anti-CD20 monoclonal antibodies at any time during pregnancy but who may be exposed to other products for the treatment of MS.

Age groups

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

728

Study design details

Setting

The study population will include 2 internal cohorts of pregnant individuals with MS and 1 “external cohort” of unexposed women without MS representing the general population in the US.
The internal study population will include 2 cohorts of pregnant individuals with MS: one cohort that is exposed to BRIUMVI™ and 1 cohort that is unexposed to BRIUMVI™ but that may be exposed to other products for the treatment of MS.

Comparators

Other DMTs

Outcomes

The primary and secondary outcomes are listed below:

Primary outcome:
- MCM

Secondary outcomes:

Pregnancy outcomes
- Minor congenital malformations
- Gestational hypertension
- Pre-eclampsia
- Eclampsia
- Gestational diabetes
- SAB
- Stillbirth
- Elective termination
- Preterm birth

Foetal/infant outcomes
- Small for gestational age (SGA)
- Postnatal growth deficiency

- Infant developmental delay
- Infant serious or opportunistic infections
- Infant hospitalizations

Data analysis plan

The BRIUMVI™ Pregnancy Registry is a prospective, observational cohort study designed to evaluate the association between BRIUMVI™ exposure during pregnancy and subsequent maternal, fetal, and infant outcomes.

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Pregnancy outcomes will be assessed throughout pregnancy, with data collection occurring at enrollment, the end of the second trimester, and pregnancy outcome. Infant outcomes will be assessed throughout the infant’s first year of life, with active data collection by the registry occurring at 4 and 12 months after delivery.

Enrolled pregnant individuals and the healthcare providers (HCPs) involved in their care or the care of their infants, if applicable, will serve as data reporters to the registry. The study is strictly observational; the schedule of office visits and all treatment regimens will be determined by HCPs.

Only data that are documented in patients’ medical records during the course of medical care will be collected. No additional laboratory tests or HCP assessments will be required as part of this

registry.

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)

Pregnancy 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