Real-World, Observational Study Assessing The Proportion Of Leukapheresed Patients with Relapsed and Refractory Multiple Myeloma That Receive Infusion of Idecabtagene Vicleucel (CA089-1097)

First published: 21/02/2025

Last updated: 21/02/2025

Study Planned

Administrative details

EU PAS number

EUPAS1000000456

Study ID

1000000456

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Switzerland

United States

Study status

Planned

Research institutions and networks

Institutions

Bristol-Myers Squibb (BMS)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Transparency and Disclosure Lead ctt.group@bms.com

Study contact

ctt.group@bms.com

Primary lead investigator

Lea Sahagun

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 05/08/2024

Study start date
Planned: 30/06/2025

Date of final study report
Planned: 30/09/2029

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bristol-Myers Squibb

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Study design:

This is a multi-center, real-world, observational cohort study that will be conducted across CAR T administering centers in the EU and US. This study will utilize the collection of data from patients with RRMM intended for treatment with ide-cel in the postmarketing setting.

Main study objective:

The primary objective of this observational study is to assess the proportion of leukapheresed patients with relapsed and refractory multiple myeloma (RRMM) who receive an infusion with commercial idecabtagene vicleucel (ide-cel) in the real-world setting.

Study drug and medical condition

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

IDECABTAGENE VICLEUCEL

Anatomical Therapeutic Chemical (ATC) code

(L01XL07) idecabtagene vicleucel

idecabtagene vicleucel

Additional medical condition(s)

Relapsed and Refractory Multiple Myeloma

Population studied

Short description of the study population

The study population will include 200 patients with RRMM aged ≥18 years who are eligible and intended for ide-cel therapy based on the local prescribing information (approved label), clinical guidelines, physician assessment and institutional protocols.

Age groups

- **Adult and elderly population (≥18 years)**

Estimated number of subjects

200

Study design details

Data analysis plan

Real-world data including demographic, clinical, and treatment data will be collected from CART administration centers in the EU and US that are enrolling RRMM patients for treatment with ide-cel. This study may apply primary data collection. Additionally, existing data collected in independent registries may also be used. The proportion of patients who receive ide-cel infusion within 6months of leukapheresis will be reported from the collected data. Its associated 95% Clopper-Pearson confidence interval will be computed. The same calculation will be performed for the high-risk and standard-risk subgroups, separately.

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.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Not applicable