Non-interventional Post-authorization Safety Study (PASS) of Patients Treated with Idecabtagene Vicleucel (ide-cel, BB2121) for Multiple Myeloma (MM) in the Postmarketing Setting (BB2121-MM-006)

First published: 03/02/2022

Last updated: 02/07/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS45152

Study ID

48309

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium

- [ ] Croatia
- [ ] Czechia
- [ ] Denmark
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Poland
- [ ] Portugal
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom
- [ ] United States

Study description

The purpose of this post-authorization safety study (PASS) is to characterize the safety profile of ide-cel in the postmarketing setting. This study will include patients from existing independent registries, such as, but not limited to, the European Society for Blood and Marrow Transplantation (EBMT) and the Center for International Blood and Marrow Transplant Research (CIBMTR). The BB2121-MM-006 study will be part of the overall ide-cel Risk Management Plan (RMP) including any required regional Pharmacovigilance Plan (PVP) outside the European Union (EU).

Study status

Ongoing

Research institutions and networks

Institutions

Bristol-Myers Squibb (BMS)

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Institution

Networks

Center for International Blood and Marrow Transplant Research (CIBMTR), European Society for Blood and Marrow Transplantation (EBMT)

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Amanda Anderson

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 26/08/2021

Actual: 26/08/2021

Study start date
Planned: 05/02/2022

Actual: 14/02/2022

Data analysis start date
Planned: 31/03/2042

Date of final study report
Planned: 31/03/2043

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bristol-Myers Squibb

Study protocol

BB2121-MM-006-prot-v1-redacted.pdf(446.6 KB)

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)

Regulatory procedure number

EMEA/H/C/004662

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

The main objective is to characterize the incidence and severity of selected adverse drug reactions (ADRs), as outlined in the Summary of Product Characteristics (SmPC), in participants treated with idecabtagene vicleucel (ide-cel) in the postmarketing setting and to monitor for potential clinically

important adverse events that have not yet been identified as part of the ide-cel safety profile.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

ABECMA

Medical condition to be studied

Plasma cell myeloma

Population studied

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

1000

Study design details

Outcomes

• All secondary malignancies • Cytokine release syndrome (CRS) grade ≥ 3 • Neurotoxicity Grade ≥ 3 • Prolonged cytopenias • Pregnancy outcome • Other adverse events (AEs) considered related to idecabtagene vicleucel, • Overall survival (OS) • Progression-free survival (PFS)

Data analysis plan

Results will be analyzed and reported descriptively and no formal hypothesis testing is carried out. Summary statistics will consist of the number and percentage of patients in each category for discrete variables, whereas for continuous variables the sample size, mean, median, standard deviation, minimum, and maximum will be given. For the primary safety endpoints, incidence proportions and incidence rates will be calculated with the appropriate time periods and methods, analyses will be carried out both with and without accounting for competing risks. For the secondary effectiveness endpoints, Kaplan-Meier estimates and curves will be generated.

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

CIBMTR United States, EBMT

Data sources (types)

Other

Data sources (types), other

Hematopoietic stem cell transplantation and cellular therapy 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

No