Post-Authorisation Safety Study (PASS) MA25101: An Observational Cohort Study of the Safety of Brentuximab Vedotin in the Treatment of Relapsed or Refractory CD30+ Hodgkin Lymphoma and Relapsed or Refractory Systemic Anaplastic Large Cell Lymphoma (ARROVEN)

First published: 28/02/2013

Last updated: 02/07/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS3583

Study ID

42799

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] Czechia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Ireland
- [ ] Italy
- [ ] Latvia
- [ ] Lithuania
- [ ] Netherlands
- [ ] Norway
- [ ] Poland
- [ ] Portugal
- [ ] Slovakia
- [ ] Slovenia
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom

Study description

This study is a Post Approval Safety Study (PASS) mandated by the European Medicines Agency. This is a multi-centre prospective, observational cohort study of the safety of brentuximab vedotin treatment in patients who have been

diagnosed with relapsed or refractory CD30+ Hodgkin Lymphoma (HL) or relapsed or refractory Systemic Anaplastic Large Cell Lymphoma (sALCL). The study will target the enrolment of approximately 300 patients (at least 50 of whom have a diagnosis of sALCL), who will be treated or are being treated with brentuximab vedotin at approximately 75-100 sites in Europe and potentially other countries outside of Europe. Patients will be enrolled over a 3-year enrolment period and the total study duration will be five years from the date of first patient enrolled. The objectives of the study are to: 1. Evaluate the occurrence of Serious Adverse Events (SAEs) and specified adverse events of special interest (AESI), both serious and non-serious, in patients actively treated for relapsed or refractory CD30+ Hodgkin Lymphoma and Relapsed or Refractory sALCL in routine practice with brentuximab vedotin 2. Identify and describe potential risk factors for peripheral neuropathy in relapsed or refractory CD30+ Hodgkin Lymphoma or Relapsed or Refractory sALCL patients treated with brentuximab vedotin

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Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 100 centres are involved in the study

Contact details

Study institution contact

Paul Dolin trialdisclosures@takeda.com

Study contact

trialdisclosures@takeda.com

Primary lead investigator

Linton Kim

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/09/2012

Actual: 04/09/2012

Study start date

Planned: 31/03/2013

Actual: 26/06/2013

Data analysis start date

Planned: 30/09/2015

Actual: 30/09/2015

Date of interim report, if expected

Planned: 30/04/2016

Actual: 30/03/2016

Date of final study report

Planned: 30/07/2020

Actual: 11/10/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Millennium Pharmaceuticals Inc.

Study protocol

MA25101_Post-Authorisation Safety Study (PASS)_Amendment 2 w MPI change.pdf (986.79 KB)

MA25101 Protocol Amend 4 2017-01-27.pdf (472.02 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 2 (specific obligation of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

Evaluate the occurrence of SAEs and specified AESIs, both serious and non-serious, in patients actively treated for relapsed or refractory CD30+ HL or relapsed or refractory sALCL in routine practice with brentuximab vedotin. Identify and describe potential risk factors for peripheral neuropathy in relapsed or refractory sALCL patients treated with brentuximab vedotin.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Post-Authorisation Safety Study (PASS), Multi-center international prospective, observational

Study drug and medical condition

Medicinal product name

ADCETRIS

Medical condition to be studied

Hodgkin's disease mixed cellularity refractory

Anaplastic large cell lymphoma T- and null-cell types refractory

Population studied

Short description of the study population

The study will aim to enrol eligible patients with relapsed or refractory CD30+ HL or sALCL, from up to 115 centers in Europe. It is estimated that approximately 300 patients (at least 50 of whom have a diagnosis of sALCL) will be eligible and agree to participate during the planned approximate52-month (4 years, 4 months) enrolment period of the study. The sample size for this study was based on the need for more information regarding the occurrence of both serious and non-serious AESI, relative to the size of the current safety database. Patients already being treated with brentuximab vedotin at the time of enrolment will be considered to be retrospectively enrolled for purposes of analysis and inclusion in the PASS.

To the extent possible, enrolment of all eligible patients at each site is expected in order to ensure representativeness of the study population.

Inclusion Criteria

To be eligible for enrolment, patients must meet all of the following criteria:

• Age at enrolment ≥ 18 years

• Clinical diagnosis (with histologic confirmation) of relapsed or refractory CD30+ HL or relapsed or refractory sALCL

• Patient is planned to start or is already receiving single agent therapy with

brentuximab vedotin as part of routine clinical care

• Willing and able to provide informed consent

Exclusion Criteria

Patients meeting ANY of the following criteria are not eligible for participation:

• Concurrent participation in an interventional clinical study

• Patients with primary cutaneous ALCL, unless the disease has transformed to systemic ALCL

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)

Special population of interest

Other

Special population of interest, other

Hodgkin lymphoma, Anaplastic large cell lymphoma (systemic) patients

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Estimated number of subjects

311

Study design details

Outcomes

The frequency, intensity and relationship to treatment will be evaluated for all reported serious adverse events (SAEs). In addition to SAEs overall, the frequency, intensity and relationship to treatment for the following adverse events of special interest (AESI) will be evaluated: Peripheral neuropathy Neutropenia Infections Hyperglycaemia Hypersensitivity reactions, All dose modifications including dose delays, temporary interruptions and permanent interruptions, and reported reason for change(s) will be summarised, and where possible the effect of modifications on safety will be explored.

Data analysis plan

Frequency and incidence proportion for all reported SAEs and AESI will be reported for patients enrolled and receiving at least one dose of treatment. Incidence rates and 95% confidence interval (CI) will also be reported for select events. Subgroup safety analyses will be performed by indication and other characteristics of interest (e.g. by age at enrolment < 65 or ≥ 65 years, number of treatment cycles). All dose modifications including dose delays, temporary interruptions and permanent interruptions, and reported reason for change(s) will be summarised, and where possible the effect of modifications on safety will be explored.

Documents

Study results

FINAL Takeda ARROVEN PASS_CSR_v3.0_27Nov2019.pdf (1.1 MB)

MA25101 - Abstract.pdf (693.93 KB)

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

Prospective patient-based data collection

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