TK011: Prospective, non-interventional, post-authorisation safety study (PASS) of Zalmoxis prescribed in patients undergoing haploidentical hematopoietic stem cell transplantation for high-risk hematological malignancies

First published: 20/12/2016

Last updated: 28/03/2022

Study Planned

Administrative details

EU PAS number

EUPAS16894

Study ID

46455

DARWIN EU® study

No

Study countries

France

Germany

Italy

Spain

Study description

The main objective of TK011 trial is to assess the short and long-term safety in routine clinical practice in adult patients affected by high-risk haematological malignancies, who receive Zalmoxis after a T-cell depleted haploidentical hematopoietic stem cell transplantation. In order to put the AEs of interest, defined by protocol, into context in a similar disease population, the background incidence of the stated important identified and potential risks will be determined in a non-randomized, concurrent control group of patients undergoing haploidentical transplantation without Zalmoxis prescription. No PASS trial will be conducted due to the withdrawal of the MAH in September 2019 Study timelines are not applicable as the PASS trial will not be conducted (inserted dates in section 3 are meant to be as "not applicable")

Study status

Planned

Research institutions and networks

Institutions

MolMed

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Networks

European Group for Blood and Marrow Transplantation (EBMT)

Contact details

Study institution contact

MolMed Clinical Director MolMed Clinical Director

Safety@molmed.com

Study contact

Safety@molmed.com

Primary lead investigator

MolMed Clinical Director MolMed Clinical Director

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/03/2020

Study start date
Planned: 01/07/2020

Data analysis start date
Planned: 01/03/2021

Date of interim report, if expected
Planned: 30/06/2021

Date of final study report
Planned: 30/06/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

MolMed

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

To characterize and determine the incidence of events of interest identified as important or potentially important risks in pts who receive Zalmoxis after haploidentical transplantation in a post-marketing setting and placing into context with the background incidence of these events in a non-randomized, concurrent control group of pts undergoing haploidentical transplantation without Zalmoxis

Study drug and medical condition

Medicinal product name

ZALMOXIS

Medical condition to be studied

Stem cell transplant

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

240

Study design details

Outcomes

GvHD, severe systemic infection, CMV/EBV, febrile neutropenia, hepatic failure, development of RCR, second cancer, development of immunological events, DMSO-related AEs, concomitant administration of ganciclovir, valganciclovir or immunosuppressive therapy and related AEs, treatment failure of ganciclovir for GvHD control, donor site reaction (local and/or systemic) and any AEs related to Zalmoxis

---

Data analysis plan

Mean, standard deviation, median, range, quartiles (for continuous data), and counts and percentages (for categorical data) will be calculated for baseline donor/patient/disease-related characteristics and treatments. The overall AE incidence will be summarized in terms of patient counts, percentages and 95% confidence intervals (CIs). Incidence will be computed as the number of patients with event onset in the interval divided by the number of patients in the ITT population. Adverse events will be classified using the MedDRA classification system. The severity of the toxicities will be graded according to the National Cancer Institute common toxicity criteria for adverse events (NCI-CTCAE) version 4.02 whenever possible. Frequency of AEs will be tabulated by MedDRA system organ class and preferred term. In the by-patient analysis, a patient

having the same event more than once will be counted only once. AEs will be summarized by worst grade

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