

# 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

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### Study ID

46455

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### DARWIN EU® study

No

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### Study countries

- France
  - Germany
  - Italy
  - Spain
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### **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")

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### **Study status**

Planned

## Research institutions and networks

### Institutions

**MolMed**

**First published:** 01/02/2024

**Last updated:** 01/02/2024

## 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](mailto: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

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**Study start date**

Planned: 01/07/2020

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**Data analysis start date**

Planned: 01/03/2021

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**Date of interim report, if expected**

Planned: 30/06/2021

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**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

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**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

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**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

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**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)
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### **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

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### **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](#)

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### 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

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No