

Post-Authorisation Registry of ELZONRIS (Tagraxofusp) in Patients With Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)

First published: 20/10/2026

Last updated: 20/10/2026

Study

Ongoing

Administrative details

EU PAS number

EUPAS1000001132

Study ID

1000001132

DARWIN EU® study

No

Study countries

 Austria

 Germany

 Italy

Study description

Unique Protocol ID: STML-401-0521

Study status

Ongoing

Contact details

Study institution contact

Stemline Trials clinicaltrials@menarinistemline.com

Study contact

clinicaltrials@menarinistemline.com

Primary lead investigator

Medical Director

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 11/02/2021

Study start date

Actual: 26/06/2024

Date of final study report

Planned: 30/06/2031

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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Study design:

STML-401-0521 is a non-interventional study that primarily aims to provide clinical effectiveness and safety data of tagraxofusp when used in accordance with the summary of product characteristics in the post-marketing setting in participants with BPDCN.

Main study objective:

The main objective of this registry study is to investigate the effectiveness and safety of tagraxofusp in the treatment of adult participants with BPDCN in the real-world clinical practice setting. No study medication will be provided by the sponsor during this study.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ELZONRIS

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

TAGRAXOFUSP

Anatomical Therapeutic Chemical (ATC) code

(L01XX67) tagraxofusp

tagraxofusp

Medical condition to be studied

Blastic plasmacytoid dendritic cell neoplasia

Population studied

Short description of the study population

Adult participants with BPDCN who are to be treated (or have recently started treatment) with tagraxofusp as first-line treatment according to the European Union summary of product characteristics in standard clinical practice setting across Europe. Participants who are relapse/refractory to prior treatment will also be investigated.

Age groups

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

- Adults (18 to < 65 years)
 - Adults (18 to < 46 years)
 - Adults (46 to < 65 years)
 - Elderly (≥ 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

80

Study design details

Setting

Key inclusion criteria for this study include:

- Diagnosed with BPDCN, confirmed by hematopathology and biomarkers (inclusive of CD123, CD4, and CD56).
- Planning to start treatment with tagraxofusp monotherapy for BPDCN at the time of, or within 6 months prior to, informed consent form (ICF) signature or

has started treatment.

Key exclusion criteria for this study include:

- Currently (or planning to) participating in another study or registry where BPDCN treatment outcomes are reported.
- Participating in an interventional clinical trial at the time of ICF signature.
- Known allergic reactions to components of tagraxofusp.

Other protocol-specified criteria apply.

Comparators

Not applicable

Outcomes

The primary outcome measures include:

1. Number of Participants Achieving Complete Response After 3 Months (+/- 1 month) of Treatment
2. Number of Participants Experiencing Capillary Leak Syndrome

The secondary outcome measures include:

1. Number of Participants Who Receive Stem Cell Transplant (SCT)
2. Progression-free Survival (PFS)
3. Overall Survival (OS)
4. Best Overall Response (BOR)
5. Duration of Response (DOR)
6. Number of Participants with Dose Interruptions and/or Requiring Administration of Intravenous Albumin Supplementation
7. Number of Participants with Adverse Events of Special Interest (AESI)
8. Number of Participants with Adverse Events (AEs)
9. Number of Doses/Cycles of Tagraxofusp Administered

Data management

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

Yes