A Prospective Real-World Study Evaluating Objective Response Rate and Duration of Response of Tazemetostat Monotherapy in Patients With Relapsed or Refractory Follicular Lymphoma Following at Least Two Prior Lines of Treatment

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Study Cancelled

Administrative details

EU PAS number

EUPAS1000000766

Study ID

1000000766

DARWIN EU® study

No

Study countries

United States

Study description

This study aims to evaluate the effectiveness of the medicine Tazemetostat following at least two lines of treatment in adults with relapsed/refractory follicular lymphoma, a slow-growing type of blood cancer that affects a kind of white blood cell called lymphocytes.

All participants will receive Tazemetostat as prescribed by their doctor in the routine clinical practice. The study will observe how participants respond to the treatment, how long the response lasts, and monitor safety, side effects, and how well participants tolerate the treatment.

The results will be analyzed based on whether or not participants have a mutation in the EZH2 gene (known as EZH2 wild-type versus mutant-type).

Study status

Cancelled

Contact details

Study institution contact

Ipsen Clinical Study Enquiries clinical.trials@ipsen.com

Study contact

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Primary lead investigator

Ipsen Medical Director

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 29/07/2025

Actual: 29/07/2025

Study start date
Planned: 16/06/2026

Date of final study report
Planned: 31/03/2032

Sources of funding

- Pharmaceutical company and other private sector

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

This is a prospective, observational, and multicenter study to evaluate the real-world disease response to oral tazemetostat monotherapy treatment for participants with R/R FL who have received at least 2 prior Line of Treatments.

Main study objective:

To describe rwORR to tazemetostat monotherapy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Tazverik

Anatomical Therapeutic Chemical (ATC) code

(L01XX72) tazemetostat

tazemetostat

Medical condition to be studied

Follicular lymphoma

Follicular lymphoma refractory

Additional medical condition(s)

Follicular lymphoma relapsed

Population studied

Short description of the study population

This study will enroll approximately 63 adult participants with relapsed or refractory follicular lymphoma (FL) grades 1, 2, or 3A.

All participants must have received at least two prior lines of systemic therapy and be prescribed tazemetostat monotherapy in accordance with the approved U.S. Prescribing Information.

The population includes both EZH2 wild-type and mutant cases, with mutation status either known at enrollment or determined during the study. Participants will be recruited from U.S.-based community oncology practices, hospital systems, and academic medical centers.

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)

Estimated number of subjects

63

Study design details

Outcomes

Primary outcome:

- Real-world Objective Response Rate (rwORR) stratified by EZH2 mutation status

rwORR is defined as the percentage of participants with a best overall response of complete response (CR) or partial response (PR), assessed by the investigator using the Lugano 2014 classification. From first dose to end of study participation, which may range from 1 day to up to 5 years.

Secondary Outcome Measure:

- Real-world Best Overall Response (rwBOR) stratified by EZH2 mutation status

rwBOR is defined as the best response assessed by the investigator using Lugano 2014 classification recorded from the start of treatment until disease progression or recurrence. From first dose to end of study participation, which

may range from 1 day to up to 5 years.
- Real-world Duration of Response (rwDOR) stratified by EZH2 mutation status
rwDOR is defined as the time from the first documented evidence of CR or PR until disease progression or death from any cause.
- Real-world Progression-Free Survival (rwPFS) stratified by EZH2 mutation status
rwPFS is defined as the time from the start of treatment to the date of first documented disease progression or death from any cause.
- Real-world Disease Control Rate (rwDCR) stratified by EZH2 mutation status
rwDCR is defined as the percentage of participants with CR, PR, or stable disease (SD) as their best response.
-Pattern of use of tazemetostat under realworld practice conditions: Starting dose, dose reductions and reasons for reduction; Duration of treatment; Treatment interruption and reasons; Treatment discontinuation and reasons; Subsequent systemic therapy
- Percentage of participants experiencing Treatment Emergent Adverse Events (TEAEs), including Adverse Drug Reactions (ADRs), Serious Adverse Events (SAEs), Adverse Events of Special Interest (AESIs), and Special Situations (SS).
From first dose until 30 days after last dose.

Data analysis plan

The primary endpoint of rwORR, defined as the proportion of participants with an objective response (CR or PR), stratified by EZH2 mutation status will be evaluated for all enrolled and treated participants, excluding screen failures (full analysis set [FAS]), evaluated based on response assessments between the first dose of tazemetostat and the date of PD or date of subsequent therapy. rwORR will be summarized using descriptive statistics along with the two-sided binomial exact 95% CIs.
The rwORR in the population of EZH2 WT participants will be estimated and tested versus the threshold of 20% using a one sample t-test. A response rate

over 20% will be considered statistically significant if the p-value for the one-sided test is less than 0.1.
Secondary effectiveness endpoints include: rwBOR, rwDOR, rwPFS, and rwDCR, all of which will be evaluated in the FAS and stratified by EZH2 mutation status.
rwBOR and rwDCR will be summarized using descriptive statistics (count and percentages) along with 95% confidence interval.
rwPFS and rwDOR will be estimated using Kaplan-Meier method.
The pattern of use of tazemetostat will be summarized descriptively using the FAS including duration of treatment, starting dose, dose reductions, interruptions, or discontinuation with the associated reasons.
Safety analysis will be performed on the overall Safety population and will be described presenting the number of events and number and proportion of participants for the different categories of adverse events.

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)

Non-interventional study

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