

Benefits of tildrakizumab treatment for Romanian patients with severe plaque psoriasis observed in real-life

Submission date 02/10/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 16/10/2025	Overall study status Ongoing	<input type="checkbox"/> Protocol
Last Edited 16/10/2025	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The skin cells in people with psoriasis grow faster than normal, which leads to a buildup that forms these patches. Normally, skin cells renew every 3 to 4 weeks, but in psoriasis this happens in just a few days. The cause of psoriasis is related to the immune system mistakenly attacking healthy skin cells, causing inflammation and faster skin cell growth. It often runs in families and can be triggered or made worse by things like infections, stress, skin injuries, smoking, obesity, and alcohol. Psoriasis affects people differently; some have mild patches, while for others it can be severe and impact their quality of life. The disease usually comes and goes in cycles, with flare-ups followed by periods of less severe symptoms. Psoriasis can be associated with other health problems, such as depression, arthritis that affects the joints, and heart or metabolic issues. Treatments aim to reduce the symptoms and improve the patient's life, often involving medications that calm the immune system and reduce inflammation. A newer type of treatment targets specific parts of the immune system that cause psoriasis. For example, tildrakizumab is a medicine that blocks a protein called IL-23 involved in the inflammation process. This treatment has been shown to be safe and effective for many patients, even those who have other health problems along with psoriasis.

Who can participate?

Patients aged over 18 years with severe psoriasis who have already been prescribed tildrakizumab (Ilumetri®) treatment

What does the study involve?

Tildrakizumab (Ilumetri®) will be administered and patient demographic data will be collected during the screening visit where available (age, gender etc). All the assessments will be performed at the start of the study and at weeks 28, 52 and end of study visit.

What are the possible benefits and risks of participating?

The results of this study may help improve the safety and performance profile of the product. There is no specific and/or direct benefit from participating in this study. Participation in this study is voluntary.

The treatment strategy for the condition will be recommended by the treating physician. Thus, the physician may prescribe an alternative to the treatment already prescribed and decide to discontinue the study participation.

Where is the study run from?

Dermatology clinics or dermatology department in tertiary care centers within the territory of Romania during routine clinical practice settings.

When is the study starting and how long is it expected to run for?

March 2023 to May 2026

Who is funding the study?

Terapia SA a SUN PHARMA Company (Romania)

Who is the main contact?

Mrs Alina Iordache, alina.iordache@cebis-int.com

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

TSP_IL_CBS20022023

Study information

Scientific Title

Real-life effectiveness, tolerability, and impact on quality of life of tildrakizumab in severe plaque psoriasis: a Romanian perspective

Acronym

REAL

Study objectives

Primary objectives:

Tildrakizumab effectiveness in subjects with severe plaque psoriasis treated according to the Summary of Product Characteristics (SmPC), current clinical practice, and National Therapeutic Protocol

Secondary objectives:

1. Percentage of super-responder patients at week 28 visit
2. Tildrakizumab effectiveness in subjects with special areas involvement (e.g., scalp, nails, genitalia, palmo-plantar)
3. Tildrakizumab tolerability profile
4. Tildrakizumab impact on quality-of-life improvement from baseline

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 15/11/2023, National Bioethics Committee for Medicinal Products and Medical Devices (Dr. Calistrat Grozovici street, no.6, district 2, Bucharest, 021105, Romania; +40 (0) 213115382; secretariat@bioetica-medicala.ro), ref: 9SNI/04.10.2023

Study design

Open-label multicenter prospective non-comparative non-interventional study

Primary study design

Observational

Study type(s)

Quality of life, Safety, Efficacy

Health condition(s) or problem(s) studied

Severe plaque psoriasis

Interventions

This non-interventional study will be conducted in patients with psoriasis by dermatologists across up to 40 centers according to routine clinical practice and provisions of the National Therapeutic Protocol. Data will be collected prospectively. Tildrakizumab (Ilumetri®) will be administered in accordance with approved SmPC. Patient demographic data would be collected during the screening visit where available (age, gender etc). All the assessments for primary and secondary objectives will be performed at baseline and periodically according to the National standards, routine clinical practice, and this study protocol.

Each patient will be followed up under the study protocol until completing 16 months of tildrakizumab treatment or until tildrakizumab treatment interruption. Each patient will attend 10 visits. These will be in line with routine clinical practice in Romania.

The recommended dose is 100 mg by subcutaneous injection at weeks 0, and 4 and every 12 weeks thereafter.

In patients with certain characteristics (e.g., high disease burden, body weight ≥ 90 kg) 200 mg may provide greater efficacy.

According to the National Therapeutic Protocol, for patients with a body weight ≥ 90 kg who after 3 months of treatment don't obtain a satisfactory response or who during therapy start losing the response, a 200 mg dose can be used for a maximum period of 6 months and only once.

Intervention Type

Other

Primary outcome(s)

Proportion of patients achieving PASI 75, defined as 75% reduction (improvement) in the Psoriasis Area and Severity Index (PASI) after treatment at week 28

Key secondary outcome(s)

1. Proportion of patients achieving PASI 75, defined as 75% reduction (improvement) in the PASI score after treatment at week 52 and end of study visit
2. Proportion of patients maintaining PASI 75 response, defined as the percentage of patients which continue to meet 75% reduction (improvement) in the PASI score after treatment at week 52 and end of study visit
3. Percentage of subjects achieving PASI 90 measured using the PASI 90% reduction (improvement) in the PASI score after treatment at week 28, 52 and end of study visit
4. Percentage of subjects achieving PASI 100 measured using the PASI 100% reduction (improvement) in the PASI score after treatment at week 28, 52 and end of study visit.
5. Special areas scores in patients with scalp psoriasis if applicable, measured using the Psoriasis Scalp Severity Index (PSSI) at baseline, week 28, 52 and end of study visit
6. Special areas scores for palm and sole psoriasis if applicable, measured using the Erythema, Scaling, Induration, Fissuring Scale (ESIFS) at baseline, week 28, 52 and end of study visit
7. Special areas score in patients with nail psoriasis if applicable, measured using the Nail Psoriasis Severity Index (NAPSI) at baseline, week 28, 52 and end of study visit
8. Absolute PASI score measured at baseline, week 28, 52 and end of study visit
9. Percentage of subjects with adverse events, drug-related treatment-emergent adverse events and change from baseline in laboratory parameters as specified in National Therapeutic Protocol, measured using AE forms at each study visit
10. DLQI score measured using the Dermatology Life Quality Index (DLQI) questionnaire at baseline, week 16, 28, 52 and end of study visit

Completion date

01/05/2026

Eligibility

Key inclusion criteria

1. Adult patients (>18 years) diagnosed with severe psoriasis
2. Eligible for Tildrakizumab (Ilumetri®) treatment according to SmPC and National Therapeutic Protocol and for whom decision of Tildrakizumab (Ilumetri®) prescription was done before enrolment in the study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

400

Key exclusion criteria

1. Patients who are not fulfilling the inclusion criteria according to the product SmPC and National Therapeutic Protocol
2. Patients participating in other trials

Date of first enrolment

16/11/2023

Date of final enrolment

23/09/2024

Locations**Countries of recruitment**

Romania

Study participating centre

Spitalul Clinic Colentina

Bucharest

Romania

-

Study participating centre

MC Medica SRL

Craiova

Romania

-

Study participating centre

SC Enderma SRL

Craiova
Romania

-

Study participating centre

Policlinica Dr Corbeanu

Craiova
Romania

-

Study participating centre

SC EVADERM HEALTH SRL

Slatina
Romania

-

Study participating centre

ULTRATONIQUE SRL

Craiova
Romania

-

Study participating centre

Advanced Research in Dermatology

Craiova
Romania

-

Study participating centre

Derma Lux

Iasi
Romania

-

Study participating centre

CMI Lauderma

Iasi
Romania

-

Study participating centre

Diaconia Medical Center

Braila
Romania

-

Study participating centre

SC New Medical 2020 SRL

Bacau
Romania

-

Study participating centre

AIS Clinics and Hospital

Bucharest
Romania

-

Study participating centre

MEHDIS DERM SRL

Constanta
Romania

-

Study participating centre

Spitalul Clinic Militar de Urgenta Dr Constantin Papilian

Cluj-Napoca
Romania

-

Study participating centre

Spitalul Clinic de Urgență Sibiu

Sibiu

Romania

-

Study participating centre

C.M.I. ZAHARIA VIORICA FLORENTINA

Bucharest

Romania

-

Study participating centre

SC Derma Clinic SRL

Fagaras

Romania

-

Study participating centre

CMI Dermatovenerologie Dr Zăvoeanu Mihaela Nicoleta

Alexandria

Romania

-

Study participating centre

Cabinet Medical Dr Bran

Timisoara

Romania

-

Study participating centre

Spitalul de Urgență Petrosani

Petrosani

Romania

-

Study participating centre

SC Medical Skin Control SRL

Constanta

Romania

-

Study participating centre

C.M.I. ZAHARIA VIORICA FLORENTINA

Bucharest

Romania

-

Study participating centre

Briana Derm SRL

Barlad

Romania

-

Study participating centre

Spitalul Judeţean de Urgenţă Satu Mare

Satu Mare

Romania

-

Study participating centre

Cabinet Medical Dermatovenerologie Orăsan Remus Ioan

Cluj-Napoca

Romania

-

Study participating centre

CMI Lauderma

Iasi

Romania

-

Study participating centre

Esderm Clinic SRL

Suceava
Romania

-

Study participating centre

Cabinet Medical CUTISSIMA

Bucharest
Romania

-

Study participating centre

CM Sanofam

Timisoara
Romania

-

Study participating centre

CMI Diana Georgeta Ciobotea

Alba-Iulia
Romania

-

Study participating centre

Derma Luxury Style

Reghin
Romania

-

Study participating centre

ESDERMCLINIC

Suceava
Romania

-

Study participating centre

Spitalul Universitar de Urgență Elias

Bucharest

Romania

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Study participating centre

Centrul Medical Euromed

Bucharest

Romania

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Study participating centre

CMI DERMATO-VENEROLOGIE Dr. Vasilut Daniela Nicoleta

Vatra Dornei

Romania

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Study participating centre

Spitalul Clinic Colentina

Bucuresti

Romania

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Study participating centre

Spitalul Clinic Colentina

Bucuresti

Romania

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Study participating centre

Cabinet Medical Dermatologic Dr Cristina Tutunaru

Craiova

Romania

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Study participating centre

SC Venus Updated SRL

Iasi

Romania

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Study participating centre

Clinica Dermatologie Spitalul Clinic Județean de Urgență Cluj-Napoca

Cluj-Napoca

Romania

-

Sponsor information

Organisation

Terapia S.A. a SUN PHARMA Company

Funder(s)

Funder type

Industry

Funder Name

Terapia S.A. a SUN PHARMA Company

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to the confidential nature of the data

IPD sharing plan summary

Not expected to be made available