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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

Registration date
16/10/2025

Overall study status
Completed

Last Edited
16/10/2025

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

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Additional identifiers

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

Primary study design
Observational

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

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 Urgenţă Sibiu
Sibiu
Romania
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Study participating centre

C.M.I. ZAHARIA VIORICA FLORENTINA
Bucharest
Romania
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Study participating centre
SC Derma Clinic SRL
Fagaras
Romania
-

Study participating centre
CMI Dermatovenerologie Dr Zăvoeanu Mihaela Nicoleta
Alexandria
Romania
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Study participating centre
Cabinet Medical Dr Bran
Timisoara
Romania
-

Study participating centre
Spitalul de Urgenţă 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
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Study participating centre
Cabinet Medical Dermatovenerologie Orăsan Remus Ioan
Cluj-Napoca
Romania
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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
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Study participating centre
ESDERMCLINIC
Suceava
Romania
-

Study participating centre
Spitalul Universitar de Urgenţă Elias
Bucharest
Romania
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Study participating centre

Centrul Medical Euromed
Bucharest
Romania
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CMI DERMATO-VENEROLOGIE Dr. Vasilut Daniela Nicoleta
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Romania
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Study participating centre
Spitalul Clinic Colentina
Bucuresti
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Study participating centre
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Study participating centre
Cabinet Medical Dermatologic Dr Cristina Tutunaru
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Study participating centre
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Romania
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Study participating centre

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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