Dermatol Ther (Heidelb) (2026) 16:701–707
https://doi.org/10.1007/s13555-026-01653-w

RESEARCH LETTER

Real-World Effectiveness and Safety of Tildrakizumab for Plaque Psoriasis: A 3-Year International Multicenter Retrospective Study

Tiago Torres · Siddhartha Sood · Orhan Yilmaz · Ronald B. Vender · Vimal H. Prajapati · Luis Puig · Matteo Megna · Angelo Valerio Marzano · Paolo Gisondi · Jose Manuel Carrascosa · Esteban Dauden · Mar Llamas-Velasco · Anna Balato · Barbara Guerra Leal · Francesca Prignano · Francesco Bellinato · Gianmarco Silvi · Eugenia Veronica Di Brizzi · Luca Potestio · Carlo Giovanni Carrera · Anna López-Ferrer · Elena Del-Alcazar · Asfandyar Mufti · Lara Valeska Maul · Stefano Piaserico · Julia-Tatjana Maul · Jensen Yeung

Received: November 3, 2025 / Accepted: January 7, 2026 / Published online: January 23, 2026

COMMENTARY

In patients with moderate-to-severe plaque psoriasis, biologic therapy has become a mainstay of treatment. Of recent agents, tildrakizumab is a monoclonal antibody targeting interleukin-23 (IL-23) that has been approved for treatment of moderate-to-severe plaque psoriasis in several countries worldwide [1]. While phase III clinical trials and subsequent open-label extension studies have evaluated its efficacy and safety, real-world evidence involving patients from routine clinical practice is limited [1, 2]. While our group previously reported real-world drug survival outcomes of up to 3 years with tildrakizumab, this

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s13555-026-01653-w.

T. Torres (✉)
Department of Dermatology, Centro Hospitalar de Santo António, Centro Hospitalar Universitário do Porto, Largo do Prof. Abel Salazar S/N, 4099-001 Porto, Portugal
e-mail: torres.tiago@outlook.com

T. Torres · B. G. Leal
Instituto de Ciências Biomédicas Abel Salazar, University of Porto, Porto, Portugal

S. Sood
Temerty Faculty of Medicine, University of Toronto, Toronto, ON, Canada

O. Yilmaz
College of Medicine, University of Saskatchewan, Saskatoon, SK, Canada

R. B. Vender
Division of Dermatology, McMaster University, Hamilton, ON, Canada

R. B. Vender
Dermatrials Research Inc. & Venderm Consulting, Hamilton, ON, Canada

V. H. Prajapati · J. Yeung
Probity Medical Research, Waterloo, Canada

V. H. Prajapati
Division of Dermatology, Department of Medicine, University of Calgary, Calgary, Canada

V. H. Prajapati
Section of Community Pediatrics, Department of Pediatrics, University of Calgary, Calgary, Canada

V. H. Prajapati
Section of Pediatric Rheumatology, Department of Pediatrics, University of Calgary, Calgary, Canada

V. H. Prajapati
Skin Health & Wellness Centre, Calgary, Canada

V. H. Prajapati
Dermatology Research Institute, Calgary, Canada

L. Puig · A. López-Ferrer
Department of Dermatology, Hospital de la Santa Creu i Sant Pau and Universitat Autònoma de Barcelona School of Medicine, Barcelona, Spain

subset analysis focuses on its effectiveness and safety [1].

We included adult patients with plaque psoriasis that received tildrakizumab from 14 centers in Canada, Spain, Italy, Portugal, and Switzerland. Patients were initiated on tildrakizumab as per standard dosing. The study design has been previously described [1]. The primary effectiveness outcome measured was absolute Psoriasis Area and Severity Index (PASI) score. A modified Non-Responder Imputation (mNRI) analysis was applied for response-related discontinuation. Safety was measured via adverse events (AEs). The study was conducted using anonymized and deidentified data in adherence with ethical standards with institutional research board (IRB) approval at the academic institutions involved.

This analysis identified 517 patients. The mean age was 50.1 (SD ± 15.8) years with 61.5% (318/517) being male (Table 1); 74.1% (383/517) and 35% (181/517) patients had previously utilized conventional systemic therapy/phototherapy or biologics, respectively. We identified 426, 315, and 148 patients who continued tildrakizumab at year 1, 2, and 3, respectively.

At 1 year ($n = 426$), 87.6% (373/426), 69.3% (295/426), and 50% (213/426) achieved absolute PASI scores ≤ 3, ≤ 1, and 0, respectively. At 2 years ($n = 315$), 80.3% (253/315), 63.2% (199/315), and 51.1% (161/315) achieved absolute PASI scores ≤ 3, ≤ 1, and 0, respectively. Finally, at 3 years ($n = 148$), 78.4% (116/148), 61.5% (91/148), and 48% (71/148) reached absolute PASI scores ≤ 3, ≤ 1, and 0, respectively (Table 2). Achievement of PASI ≤ 3 (at years 1 and 3) was found to be significantly higher in biologic-naïve versus biologic-experienced patients (Supplementary Table 1, Supplementary Table 2). Response rates were not impacted by obesity (BMI ≥ 30) status (Supplementary Table 2). During treatment, 3.1% (16/517) underwent dose escalation of tildrakizumab (from 100 to 200 mg), and 1.4% (7/517) used concomitant systemic therapies.

In this cohort of patients, 10.8% (56/517) experienced treatment-emergent AEs (TEAEs) (Table 2, Supplementary Table 3). Of these, infection was most common (5.6%, 29/517), with 0.2% (1/517) of patients requiring

M. Megna · L. Potestio
Section of Dermatology, Department of Clinical Medicine and Surgery, University of Naples Federico II, Naples, Italy

A. V. Marzano · C. G. Carrera
Dermatology Unit, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy

A. V. Marzano
Department of Pathophysiology and Transplantation, Università Degli Studi di Milano, Milan, Italy

P. Gisondi · F. Bellinato
Department of Dermatology, University of Verona, Verona, Italy

J. M. Carrascosa · E. Del-Alcazar
Servicio de Dermatología, Hospital Universitari Germans Trias i Pujol, IGTP, UAB Badalona, Barcelona, Spain

E. Dauden · M. Llamas-Velasco
Department of Dermatology, Hospital Universitario de La Princesa, Instituto de Investigación Sanitaria de La Princesa (IIS-IP), Madrid, Spain

A. Balato · E. V. Di Brizzi
Unit of Dermatology, University of Campania Luigi Vanvitelli, Naples, Italy

F. Prignano · G. Silvi
Department of Health Sciences, Section of Dermatology, University of Florence, Florence, Italy

A. Mufti · J. Yeung
Division of Dermatology, Department of Medicine, University of Toronto, Toronto, ON, Canada

A. Mufti · J. Yeung
Division of Dermatology, Department of Medicine, Sunnybrook Health Sciences Centre, Toronto, ON, Canada

L. V. Maul
Department of Dermatology, University Hospital Basel, Basel, Switzerland

L. V. Maul · J.-T. Maul
Department of Dermatology, University Hospital Zürich, Zurich, Switzerland

S. Piaserico
Department of Dermatology, University of Padua, Padua, Italy

J.-T. Maul
Faculty of Medicine, University of Zürich, Zurich, Switzerland

J. Yeung
Division of Dermatology, Department of Medicine, Women's College Hospital, Toronto, Canada

Table 1 Baseline demographic and clinical characteristics for adult patients with moderate-to-severe plaque psoriasis treated with tildrakizumab

Demographic and clinical characteristics	Value
Sex, *n* (%)	
Male	318 (61.5)
Female	199 (38.5)
Baseline age (years), mean ± SD	50.1 ± 15.8
Disease duration (years), mean ± SD	16.8 ± 12.5
Baseline BMI, mean ± SD	26.3 ± 4.3
Comorbidities, *n* (%)	
Hypertension	137 (26.5)
Dyslipidemia	126 (24.4)
Obesity	70 (13.5)
PsA	42 (8.1)
Latent tuberculosis	50 (9.7)
Hepatitis B	13 (2.5)
Hepatitis C	12 (2.3)
Inflammatory bowel disease	4 (0.8)
Smoking status, *n* (%)	
Smoker	133 (25.7)
Previous treatments, *n* (%)	
Phototherapy	146 (28.2)
Systemic non-biologic therapy	383 (74.1)
Methotrexate[†]	201 (39.1)
Cyclosporine[†]	150 (29)
Retinoids[†]	96 (18.6)
Apremilast[†]	11 (2.1)
Systemic biologic therapy	181 (35)
Adalimumab[‡]	113 (21.9)
Secukinumab[‡]	37 (7.2)
Ustekinumab[‡]	37 (7.2)
Etanercept[‡]	36 (6.7)
Ixekizumab[‡]	24 (4.6)
Risankizumab[‡]	16 (3.1)
Guselkumab[‡]	11 (2.1)
Infliximab[§]	10 (1.9)
Brodalumab[‡]	8 (1.6)
Certolizumab[‡]	2 (0.4)
Bimekizumab[‡]	1 (0.2)
Number of prior biologic treatments	
1	117 (22.6)
2	40 (7.7)
≥ 3	24 (4.6)
Baseline PASI, mean ± SD	11.5 ± 6

BMI body mass index; *n* number of patients meeting criteria; *PASI* psoriasis area and severity index; *PsA* psoriatic arthritis; *SD* standard deviation

[†]Oral route [‡]subcutaneous route [§]intravenous route

hospitalization. Malignancy was documented in 0.4% (2/517) of patients. Injection site reaction was documented in 0.6% (3/517). Regarding cardiac AEs, one patient (0.2%) received a new diagnosis of heart failure (New York Heart Association Functional Class III) during tildrakizumab treatment. No hepatic abnormalities were observed. Eighty-eight (17%) patients discontinued tildrakizumab with reasons including lack of efficacy (9.5%, 49/517) and AEs (2.3%, 12/517: infection [*n* = 6]; malignancy [*n* = 2]; lymphocytosis [*n* = 1], myalgia [*n* = 1]; uncontrolled dyslipidemia [*n* = 1]; alopecia areata [*n* = 1]). Safety data were further explored in our previously reported drug survival analysis [1].

Our real-world absolute PASI outcomes for tildrakizumab at years 1 and 3 are comparable to NRI outcomes from open-label extension studies (reSURFACE 1 and reSURFACE 2) at weeks 52 and weeks 148 [2]. A similar study from Italy (*n* = 136) is the longest real-world follow-up of tildrakizumab to date, which demonstrated 84.4% achievement of PASI ≤ 2 [3]. For 3 years, our safety data were consistent with open-label

Table 2 Effectiveness and safety outcomes for tildrakizumab treatment in adult patients with moderate-to-severe plaque psoriasis

Effectiveness and safety outcomes	Value
Effectiveness outcomes at 1 year	n/N (%)
PASI ≤ 3	373/426 (87.6)
PASI ≤ 1	295/426 (69.3)
PASI 0	213/426 (50)
Effectiveness outcomes at 2 years	
PASI ≤ 3	253/315 (80.3)
PASI ≤ 1	199/315 (63.2)
PASI 0	161/315 (51.1)
Effectiveness outcomes at 3 years	
PASI ≤ 3	116/148 (78.4)
PASI ≤ 1	91/148 (61.5)
PASI 0	71/148 (48)
	Mean ± SD
PASI after 1 year of treatment	1.1 ± 2
PASI after 2 years of treatment	1.2 ± 0.5
PASI after 3 years of treatment	1.3 ± 2.1
Safety outcomes	n/N (%)
Treatment-emergent adverse events of special interest	
Infection	29/517 (5.6)
Infection leading to hospitalization	1/517 (0.2)
Injection site reaction	3/517 (0.6)
Malignancy	2/517 (0.4)
Carcinoid tumor	1/517 (0.2)
Follicular lymphoma	1/517 (0.2)
Heart failure	1/517 (0.2)
Hepatic abnormalities	0/517 (0)

n number of patients meeting criteria; *PASI* psoriasis area and severity index; *PASI75* 75% improvement in psoriasis area and severity index from baseline; *SD* standard deviation

extension studies at the same timepoint, including for TEAEs of special interest [4, 5]. Of note, in our previous analysis of this cohort, we identified a real-world drug survival of 91.3% at 1 year, 85.3% at 2 years, and 82.4% at 3 years for patients, revealing that tildrakizumab is favorably tolerated in the long term and further supporting our effectiveness/safety results [1]. Study limitations include its small sample size, retrospective nature, a lack of available laboratory monitoring data, and a lack of available effectiveness metrics aside from PASI. Overall, our real-world data support the long-term use of tildrakizumab for plaque psoriasis.

Author Contributions. Tiago Torres and Jensen Yeung contributed to concept and design, data collection, statistical analysis, and drafting of the manuscript. Orhan Yilmaz contributed to data collection. Siddhartha Sood, Ronald Bernard Vender, Vimal H Prajapati, Luis Puig, Matteo Megna, Angelo Valerio Marzano, Paolo Gisondi, Jose Manuel Carrascosa, Esteban Dauden, Mar Llamas-Velasco, Anna Balato, Barbara Guerra Leal, Francesca Prignano, Francesco Bellinato, Gianmarco Silvi. Eugenia Veronica Di Brizzi, Luca Potestio, Carlo Giovanni Carrera, Anna López-Ferrer, Elena Del-Alcazar, Asfandyar Mufti, Lara Valeska Maul, Stefano Piaserico, and Julia Tatjana Maul contributed to data collection and drafting of the manuscript.

Funding. No funding or sponsorship was received for this study or publication of this article.

Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Conflict of interest. Tiago Torres has been an advisor, consultant, investigator and/or speaker for AbbVie, Almirall, Amgen, Arena Pharmaceuticals, Biocad, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Fresenius Kabi, Janssen, LEO Pharma, Eli Lilly, MSD, Mylan, Novartis, Pfizer, Samsung-Bioepis, Sanofi-Genzyme, Sandoz, and UCB. Tiago Torres, Luis Puig, Paolo Gisondi, Jose Manuel Carrascosa, and Anna Lopez-Ferrer are members of the editoral board of Dermatology and Therapy. Tiago Torres, Luis Puig, Paolo Gisondi, Jose Manuel

Carrascosa, and Anna Lopez-Ferrer were not involved in the selection of peer reviewers for the manuscript or any of the subsequent editorial decisions. Francesca Prignano served as advisory board member and consultant and has received fees and speaker's honoraria or has participated in clinical trials for AbbVie, Almirall, Leo Pharma, Eli-Lilly, Janssen, Novartis, Biogen, Sanofi Genzyme, UCB, and Boehringer-Ingelheim. Esteban Dauden has the following conflict of interests: Advisory Board member, consultant, grants, research support, participation in clinical trials, honorarium for speaking, with the following pharmaceutical companies: Abbvie/Abbott, Almirall, Amgen-Celgene, Johnson & Johnson/Janssen-Cilag, Leo-Pharma, Novartis, Pfizer, MSD-Schering-Plough, Lilly, UCB, Brystol-Myers and Boehringer-Ingelheim. Mar Llamas-Velasco has the following conflict of interests: Advisory Board member, consultant, grants, research support, participation in clinical trials, honorarium for speaking, with the following pharmaceutical companies: Abbvie/Abbott, Almirall, Amgen-Celgene, Boehringer-Ingelheim, Brystol-Myers, Cantabria Labs, Johnson & Johnson/Janssen-Cilag, Leo-Pharma, Kyowa-Kirin, Novartis, Lilly, UCB. Anna Balato has served as speaker and/or has received fees from Abbvie, Almirall, Amgen, BI, BMS, Eli-Lilly, Janssen, Leo-Pharma, Novartis, Sanofi, UCB. Matteo Megna has acted as a speaker or consultant for Almirall, Abbvie, Amgen, Bristol Myers Squibb, Eli Lilly, Leo Pharma, Janssen, Novartis, and UCB. Luis Puig has received consultancy/speaker's honoraria from and/or participated in clinical trials sponsored by AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Fresenius-Kabi, Horizon (DSMB), J&J Innovative Medicine, Leo-Pharma, Lilly, Novartis, Pfizer, Samsung-Bioepis, STADA, Sun-Pharma, and UCB. Angelo Valerio Marzano reports consultancy/advisory boards disease-relevant honoraria from AbbVie, Amgen, Boehringer-Ingelheim, Bristol Myers Squibb, Incyte, Leopharma, Novartis, Pfizer, Sanofi, and UCB. Paolo Gisondi has been a consultant and/or speaker for AbbVie, Almirall, Amgen, Boehringer Ingelheim, Janssen, Leo Pharma, Eli Lilly, Novartis, Pierre Fabre, Sandoz, Sanofi, and UCB. Idolazzi served as consultant and/or speaker for AbbVie, Amgen, Biogen, Merck Sharp & Dohme, Eli Lilly, Novartis, Celgene, and Sandoz Girolomoni served as consultant and/or speaker for AbbVie, Abiogen, Almirall, Amgen, Biogen, Boehringer Ingelheim, Bristol-Meyers Squibb, Celltrion, Eli Lilly, Genzyme, Leo Pharma, Novartis, OM Pharma, Pfizer, Regeneron, Samsung, Sandoz, and UCB. Carlo Giovanni Carrera has served as a board participant or speaker for Abbvie, Lilly, Janssen, Novartis, Celgene, Almirall, and Leopharma. Anna López Ferrer has received payments or honoraria for educational events, support to attend meetings, and participation in advisory boards or consultancies from Abbvie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Johnson and Johnson, Eli Lilly, Leo Pharma, Novartis and UCB. Stefano Piaserico has been a consultant and/or speaker for Abbvie, Almirall, Amgen, Bristol Myers, Janssen, LEO Pharma, Eli Lilly, Merck Sharp Dohme, Novartis, Pfizer, Sandoz, and UCB. Prof. Julia-Tatjana Maul has served as advisor and/or received speaking fees and/or participated in clinical trials sponsored by AbbVie, Almirall, Amgen, BMS, Celgene, Eli Lilly, LEO Pharma, Incyte, Janssen-Cilag, MSD, Novartis, Pfizer, Pierre Fabre, Roche, Sanofi, and UCB. Lara Valeska Maul has served as advisor and/or received speaking fees and/or grants and/or participated in clinical trials sponsored by Almirall, Amgen, Bristol-Myers Squibb (BMS), Canfield, Eli Lilly, Incyte, L' Oreal, Merck Sharp & Dohme (MSD), Novartis, Pierre Fabre, Roche, and Sanofi outside of the submitted work. Ronald Vender has been an advisor, consultant, speaker, and/or investigator for AbbVie, Actelion, Amgen, Aralez, Arcutis, Astellas, Bausch Health, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Cipher, Centocor, Dermira, Dermavant, Eli Lilly, Galderma, GSK, Innovaderm, Janssen, Kabi-Care, LEO Pharma, Merck, Novartis, Palladin, Pfizer, Regeneron, Sandoz, Sun Pharma, Takeda, UCB, and Viatris-Mylan. Vimal H. Prajapati has been an advisor, consultant, and/or speaker for AbbVie, Actelion, Amgen, Apogee Therapeutics, Aralez, Arcutis, Aspen, Bausch Health, BioJAMP/JAMP Pharma, BioScript Solutions, Boehringer Ingelheim, Bristol Myers Squibb, Canadian Psoriasis Network, Celgene, Celltrion, Cipher, CorEvitas, Eczema

Society of Canada, Eli Lilly, Galderma, GlaxoSmithKline, Homeocan, Incyte, J&J Innovative Medicine, Janssen, Johnson & Johnson, LEO Pharma, Medexus, Novartis, Organon, Paladin, Pediapharm, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharma, Tribute, and UCB; investigator for AbbVie, AnaptysBio, Apogee Therapeutics, Apollo Therapeutics, Arcutis, Arena, Asana, Bausch Health, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Concert, CorEvitas, Dermavant, Dermira, Eli Lilly, Galderma, Incyte, J&J Innovative Medicine, Janssen, LEO Pharma, Nektar Therapeutics, Nimbus Lakshmi, Novartis, Pfizer, RAPT Therapeutics, Regeneron, Reistone, Roche, Sanofi Genzyme, Sun Pharma, Takeda, UCB, and Vyne Therapeutics; and received grants from AbbVie, Bausch Health, Janssen, LEO Pharma, Novartis, and Sanofi Genzyme. Jensen Yeung has been an advisor, consultant, speaker, and/or investigator for AbbVie, Amgen, Anacor, Arcutis, Astellas, Bausche, Baxalta, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Centocor, Coherus, Dermira, Forward, Fresenius Kabi, Galderma, Incyte, Janssen, LEO Pharma, Medimmune, Merck, Novartis, Pfizer, Regeneron, Roche, Sanofi Genzyme, Sun Pharma, Takeda, UCB, and Xenon. Asfandyar Mufti has been a speaker for AbbVie and Janssen. Jose-Manuel Carrascosa has received consultancy/speaker's honoraria from and/or participated in clinical trials sponsored by AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, J&J. Leo-Pharma, Lilly, Novartis, Pfizer, Pfizer, Galderma, Sanofi and UCB. The remaining authors (Siddhartha Sood, Orhan Yilmaz, Jose Manuel Carrascosa, Gianmarco Silvi, Eugenia Veronica Di Brizzi, Barbara Guerra Leal, Elena Del-Alcazar, Francesca Bellinato, Luca Potestio) have no relevant disclosures of interest to declare.

Ethical Approval. The study was conducted using anonymized and deidentified data in adherence with ethical standards with institutional research board (IRB) approval at academic insitutions involved.

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