

## Effectiveness and Safety of Deucravacitinib in Moderate-to-Severe Psoriasis: an Italian Multicenter Real-Life Study in the Lazio Region

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**ABSTRACT Introduction:** Psoriasis is a chronic, immune-mediated disease that significantly impacts patients' quality of life. Deucravacitinib, an oral selective TYK2 inhibitor, has shown promising efficacy and safety in phase 3 trials, but real-world evidence remains limited.

**Objective:** To evaluate the effectiveness and safety of deucravacitinib in moderate-to-severe psoriasis in an Italian real-life multicenter cohort.

**Methods:** A retrospective multicenter study was conducted across nine dermatology units in the Lazio region, including 49 adult patients treated with deucravacitinib. Clinical outcomes were assessed using the Psoriasis Area and Severity Index (PASI), Nail Psoriasis Severity Index (NAPSI), Disease Activity index for Psoriatic Arthritis (DAPSA), and Dermatology Life Quality Index (DLQI) at baseline, week 8, and week 16.

**Results:** Mean PASI scores significantly improved, from 11.4 at baseline to 4 at week 8 and to 1.7 at week 16. PASI 75 and PASI 90 responses were achieved by 31 and 13 patients, respectively. DLQI improved from 12 to 1 at week 16, indicating substantial quality-of-life gains. Clinical improvement was consistent in difficult-to-treat areas (scalp, nails, palmoplantar regions) and among patients with psoriatic arthritis. No significant difference emerged between biologic-naïve and biologic-experienced groups. Treatment was well tolerated, with only mild adverse events reported.

**Conclusion:** This real-world study confirms deucravacitinib as an effective and safe oral treatment for moderate-to-severe psoriasis, providing rapid and sustained clinical improvement and enhanced patient quality of life.

## Introduction

Psoriasis is a chronic inflammatory skin disease characterized by well-demarcated erythematous scaly lesions typically affecting the elbows, knees, scalp, and lumbosacral region. Beyond its visible cutaneous manifestations, psoriasis is increasingly recognized as a systemic condition, frequently associated with comorbidities such as psoriatic arthritis, metabolic syndrome, type 2 diabetes mellitus, and mood disorders [1]. Its prevalence varies geographically, with higher rates observed in Northern Europe and North America, where it affects up to 2–3% of the population [2]. Over recent decades, advances in the understanding of psoriasis pathophysiology have highlighted the central role of the IL-23/Th17 axis, which drives a sustained inflammatory response and promotes keratinocyte hyperproliferation [3]. Specifically, interleukin 23 promotes the differentiation of T-helper 17 (Th17) lymphocytes, which release pro-inflammatory cytokines such as IL-17A, IL-17F, and IL-22, key mediators responsible for chronic inflammation and the epidermal alterations seen in psoriasis [4,5]. This pathogenetic framework has paved the way for the development of targeted therapies, both biologics and small molecules, able to selectively modulate the immune pathways involved [6]. Although biologic agents have revolutionized the management of moderate-to-severe psoriasis, an unmet clinical need remains due to factors such as the need for parenteral administration, variable treatment response, and tolerability concerns in certain patient populations. In this context, **deucravacitinib** emerges as a novel oral therapy belonging to the class of selective tyrosine kinase 2 (TYK2) inhibitors [7]. Unlike first-generation JAK inhibitors, deucravacitinib exerts its effect through allosteric inhibition by binding the regulatory (pseudokinase) domain of TYK2 [7]. This mechanism

selectively blocks signaling downstream of key cytokines, including IL-12, IL-23, and type I interferons, while sparing JAK1, JAK2, and JAK3, potentially leading to a more favorable safety profile [8]. The phase 3 clinical trials POETYK PSO-1 and POETYK PSO-2 have demonstrated the efficacy of deucravacitinib in the treatment of moderate-to-severe plaque psoriasis, with significantly greater clinical responses compared to placebo and apremilast, as measured by PASI 75 and static Physician's Global Assessment (sPGA) 0/1 at week 16 [9,10]. The approval of deucravacitinib thus represents a major step forward in the therapeutic landscape, offering patients an effective, targeted, well-tolerated oral treatment option.

## Objectives

The aims of this study were to evaluate the effectiveness and safety of deucravacitinib in patients with moderate-to-severe plaque psoriasis in real clinical practice.

## Materials and Methods

A multicenter retrospective real-world data study was conducted on 49 patients with moderate-to-severe psoriasis based on routine clinical practice across hospitals in the Lazio region of Italy. The study involved nine centers, as detailed in Table 1. The primary endpoint of the study was to evaluate the effectiveness of deucravacitinib over time by assessing changes in psoriasis severity using the Psoriasis Area and Severity Index (PASI). Mean PASI scores were recorded at baseline, week 8, and week 16. Additionally, improvement in psoriatic arthritis symptoms, when present, was assessed using the Disease Activity Index in Psoriatic Arthritis (DAPSA) at the same time points. Secondary endpoints included clinical improvement

across different body areas and phenotypic manifestations (scalp, nails, palmoplantar, guttate psoriasis) using the Physician Global Assessment (PGA0-3), and in the case of nail psoriasis by Nail Psoriasis Severity Index (NAPSI). Additionally, treatment efficacy was compared between biologic-naïve and biologic-experienced patients. During the study, the drug safety profile was also assessed through the monitoring of

adverse events, and the evaluation of deucravacitinib's impact on patients' quality of life using the Dermatology Life Quality Index (DLQI) at baseline, week 8, and week 16. Continuous variables are described using mean, median, and standard deviation, whereas discrete variables are reported as absolute and relative frequencies. An UpSet plot was used to illustrate the frequency and intersection of affected anatomical sites by psoriasis. An ANOVA model was employed to evaluate the reduction in PASI scores over time in biologic-naïve and biologic-experienced patients.

**Table 1. Participating centers in the Lazio region.**

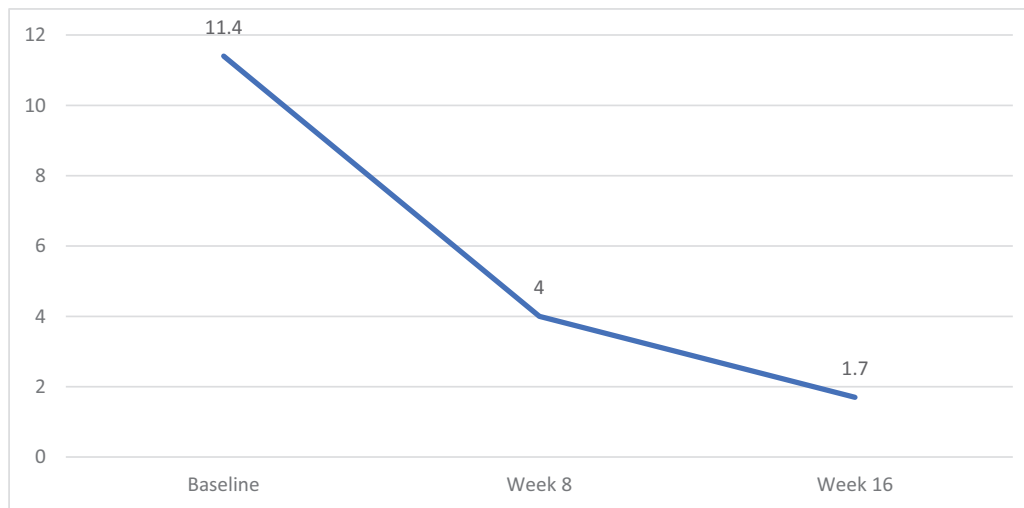
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UOS of Dermatology Campus Bio-medico of Rome

### Patients' Baseline Characteristics and Involvement

Data for this study were collected from nine dermatology centers located in the Lazio region of Italy, as detailed in Table 1. A total of 49 patients were enrolled, with a mean age of 49.10 years (standard deviation (SD)=17.14). The study population consisted of 29 males (59.18%) and 20 females (40.82%). The mean body weight was 74.20 kg (SD=13.49), and the mean body mass index (BMI) was 25.96 kg/m<sup>2</sup> (SD=3.99). Regarding psoriasis phenotypes, all patients reported plaque psoriasis; in addition, five (10.20%) had concomitant guttate psoriasis and eight (16.33%) had palmoplantar psoriasis. Moreover, five patients (10.20%) were also diagnosed with psoriatic arthritis (PsA) (Figure 1). The



**Figure 1.** (A) Clinical presentation of guttate psoriasis lesions at baseline and (B) after 16 weeks of treatment with deucravacitinib. (C) Clinical presentation of lesions of the trunk at baseline and (D) after 16 weeks. (E,F,G) Clinical presentation of lesions of down limbs at baseline. (H,I,L) Clinical presentation of down limbs after 16 weeks. (M,N) Clinical presentation of scalp involvement at baseline and (O,P) after 16 weeks of treatment with deucravacitinib. (Q) Clinical presentation of nail lesions at baseline and (R) after 16 weeks of treatment with deucravacitinib.



**Figure 2.** Trend of Psoriasis Area and Severity Index (PASI) scores over time.

mean age at psoriasis onset was 35.47 years (SD=18.54), whereas among those with PsA, the mean age at onset was 42.60 years (SD=18.64). Disease localization was most frequently observed on the scalp and/or neck in 28 patients (57.14%), upper limbs in 37 (75.51%), lower limbs in 37 (75.51%), and the trunk in 31 (63.27%) (Figure 2). Nail involvement was noted in six patients (12.24%), while inverse psoriasis affecting intertriginous areas was reported in three cases (6.12%). In most cases, multiple body sites were affected simultaneously, reflecting the clinical heterogeneity and complexity of the disease. With regard to comorbidities, 12 patients (24.49%) were diagnosed with hypertension, two (4.08%) with type 2 diabetes mellitus, and 17 (34.69%) with dyslipidemia. Additionally, 18 patients (36.73%) presented with other relevant conditions, including obesity, metabolic syndrome, thyroid disorders, and cardiovascular disease. A detailed summary of the demographic and clinical characteristics of the study cohort is provided in Table 2.

### Bio-Naïve versus Bio-Experienced

The study included a total of 49 adult patients diagnosed with moderate-to-severe plaque psoriasis who initiated treatment with deucravacitinib. Among these, 19 individuals (38.78%) had a history of prior exposure to conventional systemic therapies. In particular, seven patients had previously been treated with cyclosporine, eight with methotrexate, and four with acitretin. None of the patients had received dimethyl fumarate. Additionally, three patients had undergone narrowband UVB phototherapy. Prior biological therapy had been administered to seven patients (14.29%) before starting deucravacitinib. Of these, two had previously received adalimumab, one had been treated with secukinumab, one with ixekizumab, and three with risankizumab. Moreover, two patients had been treated with apremilast.

**Table 2. Clinical and demographic characteristics of the sample (N=49).**

Sex (N; %)	N	%
M	29	59.18
F	20	40.82
Age (mean; SD)	49.10	17.14
BMI (mean; SD)	25.96	3.99
Subtype of psoriasis (multiple options) (n; %)	N	%
Plaque	49	100
Guttate	5	10.20
Palmoplantar	8	16.33
PsA	5	10.20
Topographic psoriasis localizations (multiple options) (n; %)		
Scalp and/or neck	28	57.14
Upper limbs	37	75.51
Lower limbs	37	75.51
Trunk	31	63.27
Nails	6	12.24
Inverse psoriasis	3	6.12
PsO onset age (years) (mean; SD)	35.47	18.54
PsA onset age (years) (mean; SD)	42.60	18.64
Comorbidities (N; %)		
Yes	29	59.18
No	20	40.82
Comorbidities (multiple options) (N; %)		
Hypertension	12	24.49
Dyslipidemia	17	34.69
Diabetes mellitus	2	4.08
Other	18	36.73

Abbreviations: SD: standard deviation; BMI: body mass index; PsO: psoriasis; PsA: psoriatic arthritis.

## Results

In the study population (N=49), the mean Psoriasis Area and Severity Index (PASI) score decreased from 11.4 at baseline to 4 at week 8 (N=40) and to 1.7 at week 16 (N=31), indicating a marked and clinically significant reduction in psoriasis severity Fig.3. PASI 75 and PASI 90 improvement were achieved at week 16 in 31 and 13 patients respectively. Involvement of difficult-to-treat areas (scalp, nails, palmoplantar regions) was assessed using the Physician's Global Assessment (PGA). Twenty-eight patients presented with scalp involvement, for whom the mean PGA score improved from 3 at baseline to 1 at week 8 and 0 at week 16.

Nail involvement was evaluated using both PGA and the Nail Psoriasis Severity Index (NAPSI). In patients with nail disease (N=6), the mean PGA score decreased from 2 at baseline to 1 at week 8 and 1 at week 16. Correspondingly, the mean NAPSI score decreased from 23 at baseline to 16 at week 8 and 12 at week 16.

The therapeutic efficacy of deucravacitinib in guttate psoriasis was also evaluated. Among the study cohort, five of the 49 patients presented with concomitant guttate psoriasis (Figure 3). In this subgroup, the mean Physician's Global Assessment (PGA) score declined from 3 at baseline to 1 at week 8, reaching 0 by week 16. Notably, all five patients achieved complete skin clearance (PASI 100) by week 16. Psoriatic arthritis (PsA) was assessed using the Disease Activity Index in Psoriatic Arthritis (DAPSA); five patients in the cohort had joint involvement. During treatment with deucravacitinib, the mean DAPSA score improved from 15.0 at baseline to 5 at week 8 and to 4 at week 16.

The trend in PASI scores between bio-naïve and bio-experienced patients showed no statistically significant

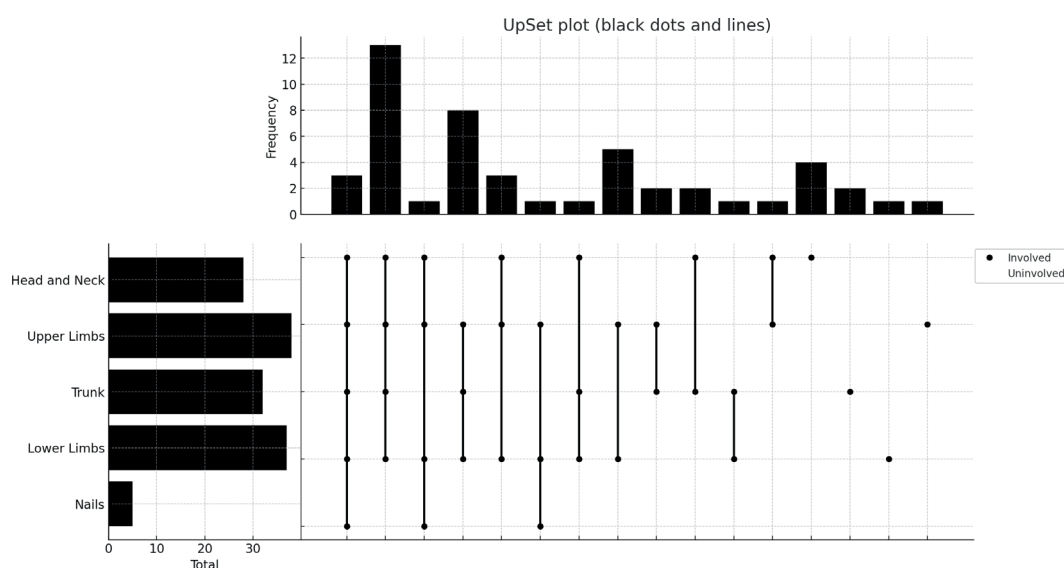
difference between the two groups. Repeated measures ANOVA was performed, and pairwise comparisons yielded p-values of 0.128 at baseline, 0.918 at week 8, and 0.996 at week 16. These results indicate the absence of any significant difference between the groups at any time point.

An additional secondary endpoint was health-related quality of life, assessed with the Dermatology Life Quality Index (DLQI). Mean DLQI scores improved from 12 at baseline to 4 at week 8 and to 1 at week 16, reflecting a substantial reduction in disease burden.

Treatment was generally well tolerated. Only three patients experienced treatment-related adverse events: one developed a mild acneiform eruption, while two reported mild respiratory tract infections. No adverse event led to treatment discontinuation.

## Discussion

Psoriasis is a chronic immune-mediated inflammatory skin disorder that affects approximately 2–3% of the global population and has a considerable impact on patients' quality of life and psychological health [1,2]. Psychosocial stress is a well-documented trigger for disease onset and exacerbation, underlining the need for a multidisciplinary and individualized management approach. Over the past decade, advances in biologics and small molecules targeting specific immune pathways have significantly improved the treatment landscape for moderate-to-severe plaque psoriasis [11]. Among emerging therapies, deucravacitinib has shown promising results in both clinical trials and early real-world studies [12]. By selectively modulating IL-12, IL-23, and type I interferon signaling via allosteric inhibition of the TYK2 pseudokinase domain, deucravacitinib offers



**Figure 3.** Distribution and overlap of psoriasis involvement across body regions. The UpSet plot illustrates the frequency and intersection of affected anatomical sites.

a novel mechanism of action with a potentially favorable safety profile [13]. The pivotal POETYK PSO-1 and PSO-2 trials demonstrated its superiority over placebo and apremilast in achieving PASI 75 and sPGA 0/1 responses at week 16 [9,10]. In our multicenter real-world cohort of 49 patients with moderate-to-severe plaque psoriasis, we observed a rapid and sustained improvement in disease severity, with mean PASI scores decreasing from 11.4 at baseline to 4 at week 8 and 1.7 at week 16. These results are consistent with phase 3 trial data, which reported PASI 75 responses in 58.4% and 53.0% of patients at week 16 in the PSO-1 and PSO-2 trials, respectively [9,10]. Additionally, the mean DLQI score significantly improved, from 12 at baseline to 1 at week 16, highlighting the positive impact of deucravacitinib on patients' quality of life, beyond clinical clearance. Our findings also highlight the effectiveness of deucravacitinib in treating difficult-to-treat psoriasis areas. Notable clinical improvements were observed in areas such as the scalp, palmoplantar regions, and particularly the nails, traditionally considered challenging due to their limited and slow response to therapy. Nail involvement, often associated with considerable functional and psychological burden, showed significant improvement, with mean NPSI scores decreasing from 23 to 12 over 16 weeks. These results further support the potential of TYK2 inhibition in targeting recalcitrant manifestations of psoriasis [14]. A subset of patients in our cohort had concomitant PsA, and although small, the observed improvement in joint symptoms is encouraging. This observation is in line with findings from a phase 2 trial evaluating deucravacitinib in PsA, where clinically meaningful improvements in joint and skin endpoints were reported [15]. Regarding safety, deucravacitinib was well tolerated in our population. No serious adverse event occurred, and no patient discontinued therapy due to treatment-related issues. This is consistent with clinical trial data, which reported low rates of adverse events without significant laboratory abnormalities [13]. The favorable safety profile, coupled with oral administration, may enhance adherence and expand treatment accessibility. Deucravacitinib also showed a rapid onset of efficacy in our cohort, consistent with a recent analysis of the POETYK PSO-1 and PSO-2 trials, which reported significant PASI improvement versus placebo as early as week 1, with sustained responses across PASI 75/90/100 and sPGA 0/1 up to week 52 [16]. This supports our observation of early clinical improvement and underlines the long-term reliability of TYK2 inhibition. Overall, our real-world findings corroborate and extend data from controlled trials, highlighting deucravacitinib as an effective and safe treatment option for moderate-to-severe plaque psoriasis. Its ability to target multiple psoriasis phenotypes, favorable impact on quality of life, and consistent efficacy across

psoriasis and psoriatic arthritis support its role as a valuable addition to current treatment algorithms.

## Limitations

Some limitations of this study should be acknowledged. Its retrospective design, relatively small sample size, and limited follow-up period may restrict the generalizability of the results. Future longitudinal studies with larger patient cohorts and longer observation periods will be essential to fully elucidating the long-term efficacy, durability of response, and safety of deucravacitinib in routine clinical practice.

## Conclusion

The current study contributes valuable real-world evidence to the expanding literature on deucravacitinib in the management of moderate-to-severe plaque psoriasis. These findings reinforce the clinical relevance of targeting the TYK2 signaling pathway and support the role of deucravacitinib as a novel, effective, well-tolerated oral therapeutic option. Clinical trial results, together with emerging real-world data, suggest that deucravacitinib can provide meaningful and sustained improvements in skin clearance, symptom burden, and patient quality of life, thus offering a promising addition to the current treatment landscape.

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