# Real-world comparative effectiveness of deucravacitinib vs apremilast at 6 months for plaque psoriasis: skin clearance outcomes from the RePhlect study

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## Synopsis


- Deucravacitinib, a first-in-class, oral, selective tyrosine kinase 2 (TYK2) inhibitor is approved in multiple countries for the treatment of adults with moderate to severe plaque psoriasis[1,2]
- Pivotal phase 3 trials, POETYK PSO-1 (NCT03624127) and POETYK PSO-2 (NCT03611751)[3,4] have demonstrated that deucravacitinib was significantly more efficacious than placebo and apremilast and was well tolerated in patients with moderate to severe plaque psoriasis
  - Deucravacitinib has also demonstrated long-term maintenance of efficacy and a consistent safety profile through 5 years of continuous treatment[5]
- The Registry of Psoriasis Health Outcomes: a Longitudinal Real-world Collaboration Study (RePhlect; NCT05744466) is designed to confirm the clinical profile of deucravacitinib by assessing its usage in a more diverse, real-world population of patients with psoriasis across North America (US and Canada), Japan, the United Kingdom, Germany, and France[6]
- This study focused on the RePhlect North American cohort, a population of adults with plaque psoriasis from real-world dermatology practices in the United States and Canada, with participants enrolled from the CorEvitas Psoriasis Registry[7]


## Objective

- This analysis compared skin clearance outcomes of deucravacitinib vs apremilast at 6 months after treatment initiation among adult patients with plaque psoriasis in the RePhlect North American region

## Methods

### Study design

- RePhlect North America is a multicenter, prospective, observational, real-world study that included data from the CorEvitas Psoriasis Registry
  - The Registry enrolls adults from the US and Canada who have dermatologist-diagnosed plaque psoriasis
  - Longitudinal follow-up data were collected during routine clinical visits using CorEvitas Psoriasis Registry questionnaires
  - Data collected through December 2024 were included in this analysis

### Patient population

- Patients from the CorEvitas Psoriasis Registry with plaque psoriasis who initiated treatment with deucravacitinib or apremilast and were followed prospectively (**Figure 1**)
  - Patients initiated deucravacitinib between September 9, 2022, and July 10, 2024
  - Apremilast was initiated between May 1, 2020, and July 10, 2024

**Figure 1. Inclusion and exclusion criteria**

**Inclusion criteria**

- **Started therapy** at a CorEvitas Psoriasis Registry visit (baseline)
- **Newly initiating** deucravacitinib[a] or apremilast[b] without concurrent use of any other systemic therapy for psoriasis
- Had **no missing** baseline characteristics or outcomes

**Exclusion criteria**

- **Participation** in an interventional clinical trial with a nonmarketed or marketed investigational drug
- **Restart of treatment** with study-eligible therapies previously received at any time during patient's treatment history

[a]Initiated treatment between September 9, 2022, and July 10, 2024. [b]Initiated treatment between May 1, 2020, and July 10, 2024.

### Outcomes of interest

- Body surface area (BSA) ≤3%
- Investigator's Global Assessment (IGA) 0/1 response
- Psoriasis Area and Severity Index (PASI) ≤3
- National Psoriasis Foundation (NPF) target and acceptable responses
  - Patients were classified as NPF acceptable responders if they had BSA ≤3% or ≥75% improvement in BSA from baseline and were classified as NPF target responders if they had BSA ≤1%

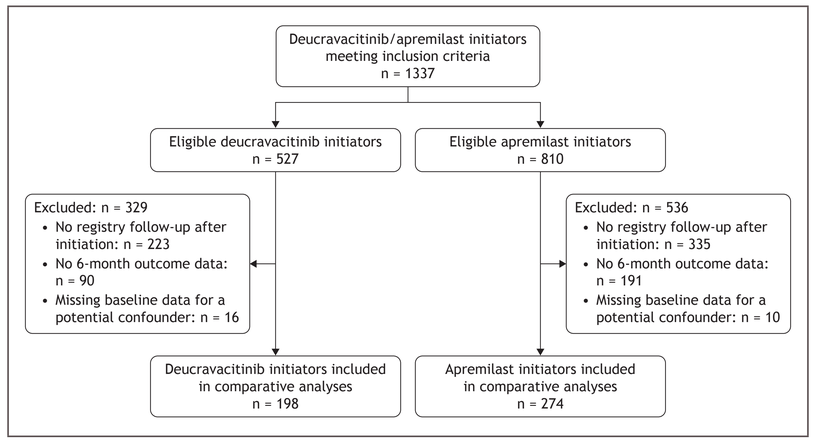
### Statistical analysis

- Comparative effectiveness was evaluated using mixed-effects regression models that included treatment groups, time, and their interaction
  - Absolute and relative changes in risk were expressed as risk differences (RDs) and risk ratios (RR)
- Entropy score weights were used to balance baseline factors, including:
  - Body mass index (BMI)
  - Psoriasis duration (years)
  - Biology therapy experience
  - BSA
  - History of psoriasis in a difficult-to-treat area
  - IGA
  - Dermatology life Quality Index (DLQI)
  - Age (years)
  - Sex
  - Race
  - PASI
  - Itch/Pruritus (visual analog scale [VAS]: 0-100)
  - Psoriatic arthritis (PsA)
- Patients who discontinued or had an add-on systemic therapy before 6 months were considered as a nonresponse on outcomes

## Results

- Overall, 1337 patients from the CorEvitas Psoriasis Registry met inclusion criteria (**Figure 2**)
  - Of these, 472 patients (198 deucravacitinib initiators and 274 apremilast initiators) with psoriasis had data available at baseline and at 6-month follow-up and were included in this comparative analysis

**Figure 2. Attrition table**




### Baseline comparisons

- At baseline and after entropy balancing, 55.7% of patients were female, 67.8% were White, and mean age was 52.4 years (**Table 1**)

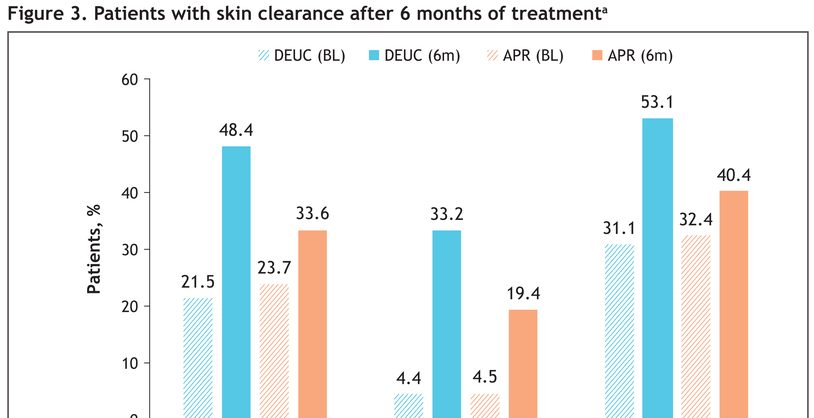
**Table 1. Baseline demographic and clinical characteristics**

| Characteristics | Unbalanced | | Balanced[a] | |
|---|---|---|---|---|
| | DEUC (n = 198) | APR (n = 274) | DEUC (n = 198) | APR (n = 274) |
| **Demographic characteristics** | | | | |
| **Age (years)** | | | | |
| Mean (SD) | 53.2 (15.6) | 51.9 (16.2) | 52.4 (16.6) | 52.4 (15.9) |
| **Female, n (%)** | 113 (57.1) | 150 (54.7) | 110.3 (55.7) | 152.7 (55.7) |
| **White, n (%)** | 156 (78.8) | 164 (59.9) | 134.2 (67.8) | 185.8 (67.8) |
| **BMI category, n (%)** | | | | |
| Underweight/normal | 36 (18.2) | 59 (21.5) | 39.9 (20.1) | 55.1 (20.1) |
| Overweight | 81 (40.9) | 79 (28.8) | 67.1 (33.9) | 92.9 (33.9) |
| Obesity | 81 (40.9) | 136 (49.6) | 91.0 (46.0) | 126.0 (46.0) |
| **Clinical characteristics** | | | | |
| **PsO duration (years)** | | | | |
| Mean (SD) | 15.3 (13.3) | 8.3 (11.3) | 11.2 (12.3) | 10.9 (12.3) |
| **Biologic naive, n (%)** | 112 (56.6) | 231 (84.3) | 143.9 (72.7) | 199.1 (72.7) |
| **PsA (dermatologist identified), n (%)** | 66 (33.3) | 73 (26.6) | 58.3 (29.4) | 80.7 (29.4) |

[a]Entropy score balancing was used to balance patient characteristics between treatment groups to control for confounding. Weights for entropy score balancing were derived from a model that included BMI, psoriasis duration, biologic therapy experience, BSA, IGA, DLQI, history of psoriasis in a difficult-to-treat area, age, sex, race, PASI, itch/pruritus, and psoriatic arthritis.
APR, apremilast; BMI, body mass index; BSA, body surface area; DEUC, deucravacitinib; DLQI, Dermatology Life Quality Index; IGA, Investigator's Global Assessment; PASI, Psoriasis Area and Severity Index; PsA, psoriatic arthritis; PsO, psoriasis; SD, standard deviation.

- After entropy score weighted regression modeling, 48.4% of the deucravacitinib group vs 33.6% of the apremilast group had BSA ≤3% at 6 months, representing a RR of 1.44 (95% confidence interval [CI] 1.08-1.80; $P = 0.018$; **Figure 3**)
- At 6 months, patients in the deucravacitinib group were 1.71 times (95% CI 1.12-2.30; $P = 0.019$) more likely to have IGA 0/1 and 1.32 times (95% CI 1.02-1.61; $P = 0.035$) more likely to have PASI ≤3 than patients in the apremilast group (**Figure 3**)

**Figure 3. Patients with skin clearance after 6 months of treatment[a]**

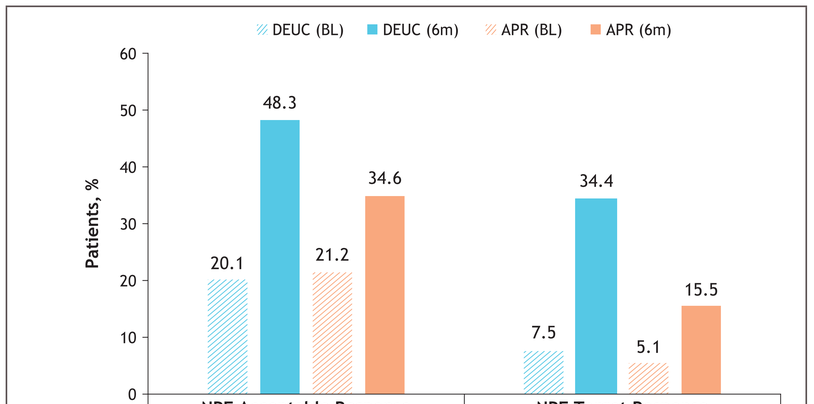



| | BSA ≤3 | IGA 0/1 | PASI ≤3 |
|---|---|---|---|
| **RR[b] (95% CI)** | 1.44 (1.08-1.80) | 1.71 (1.12-2.30) | 1.32 (1.02-1.61) |
| ***P* value** | 0.018 | 0.019 | 0.035 |
| **RD[c] (95% CI)** | 0.15 (0.04-0.25) | 0.14 (0.05-0.23) | 0.13 (0.02-0.23) |
| ***P* value** | 0.005 | 0.003 | 0.016 |

[a]All estimates are from entropy score balanced regression models. [b]Reference group = APR. [c]Risk difference >0 indicate better DEUC response.
6m, 6 months after initiation; APR, apremilast; BL, baseline; BSA, body surface area; CI, confidence interval; DEUC, deucravacitinib; IGA 0/1, Investigator's Global Assessment score of 0 or 1; PASI, Psoriasis Area and Severity Index; RD, risk difference; RR, risk ratio.

- NPF acceptable response was 1.40 times (95% CI 1.04-1.75; $P = 0.028$) more likely and NPF target response was 2.21 times (95% CI 1.37-3.05; $P = 0.005$) more likely in patients in the deucravacitinib group vs the apremilast group (**Figure 4**)

**Figure 4. Patients with NPF acceptable and target response[a] after 6 months of treatment**




| | NPF Acceptable Response | NPF Target Response |
|---|---|---|
| **RR[b] (95% CI)** | 1.40 (1.04-1.75) | 2.21 (1.37-3.05) |
| ***P* value** | 0.028 | 0.005 |
| **RD[c] (95% CI)** | 0.14 (0.03-0.24) | 0.19 (0.10-0.28) |
| ***P* value** | 0.011 | <0.001 |

[a]Patients were classified as NPF acceptable responders if they had BSA ≤3% or ≥75% improvement in BSA from baseline and were classified as NPF target responders if they had BSA ≤1%. [b]Reference group = APR. [c]Risk difference >0 indicates better DEUC response.
6m, 6 months after initiation; APR, apremilast; BL, baseline; CI, confidence interval; DEUC, deucravacitinib; NPF, National Psoriasis Foundation; RD, risk difference; RR, risk ratio.

### Strengths

- Use of data from the multicenter, longitudinal CorEvitas Psoriasis Registry allowed for comparisons of outcomes at treatment initiation and follow-up, thus overcoming challenges faced with other real-world data sources such as claims records
- This study was designed to reflect the highest quality standards of real-world evidence generation and to complement findings from randomized clinical trials
- Entropy score weighting was used to balance baseline characteristics that may have impacted 6-month outcomes between treatment groups

### Limitations

- Patients who discontinued or switched therapy were imputed as nonresponders; results should be considered as conservative estimates compared with other imputation strategies
- Loss-to-follow-up rates at 6 months were ~65% across both treatment groups, potentially driven by favorable treatment outcomes at 6 months

## Conclusions

- Findings from this North American-based real-world registry indicate that patients receiving deucravacitinib had statistically significantly greater improvements across skin clearance outcomes 6 months after initiating treatment than patients receiving apremilast
- These results build on findings from the phase 3 pivotal studies, which demonstrated superior efficacy of deucravacitinib over apremilast[3,4]

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7. Lebwohl M, et al. Presented at the 32nd European Academy of Dermatology & Venereology Congress; 11-14 October 2023; Berlin, Germany.


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