

Real-World Effectiveness of Upadacitinib in Atopic Dermatitis Based on Prior Exposure to Biologic Therapy: 6-month Interim Analysis of the Multicountry AD-VISE Study

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Learning Objective: Assess upadacitinib effectiveness in atopic dermatitis in clinical practice based on prior biologic therapy exposure.



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Background and Methods

Introduction/Background

- Upadacitinib (UPA) is an oral, selective Janus Kinase inhibitor approved across multiple countries, with variations in indications/posology across countries
- In clinical trials, UPA has demonstrated high levels of skin clearance and itch relief for the treatment of moderate-to-severe atopic dermatitis (AD); previously published safety data have shown a favorable benefit–risk profile¹⁻³
- AD-VISE (NCT05081557) is an ongoing observational, prospective, multicountry study that explores real-world usage patterns and effectiveness of UPA 15 mg and 30 mg in adults and adolescents with AD for up to 2 years⁴
- Here, we present effectiveness results for UPA in clinical practice, based on prior biologic therapy exposure assessed at baseline

Methods

- This 6-month interim data analysis (data cutoff: January 16, 2025) included adolescents and adults who enrolled at least 6 months prior to the cut off date or had discontinued the study
- Patients were stratified as bionative (BN) or bioexperienced (BE), based on prior biologic therapy exposure
- Key outcomes evaluated included the validated Investigator Global Assessment for AD (vIGA-AD) 0/1 (primary), Eczema Area and Severity Index (EASI), Worst Pruritus Numerical Rating Scale (WP-NRS), achievement of minimal disease activity ($EASI \leq 3$ and WP-NRS 0/1), Dermatology Life Quality Index (DLQI), Patient Oriented Eczema Measurement (POEM), and AD Control Tool (ADCT), all assessed using clinically relevant response thresholds

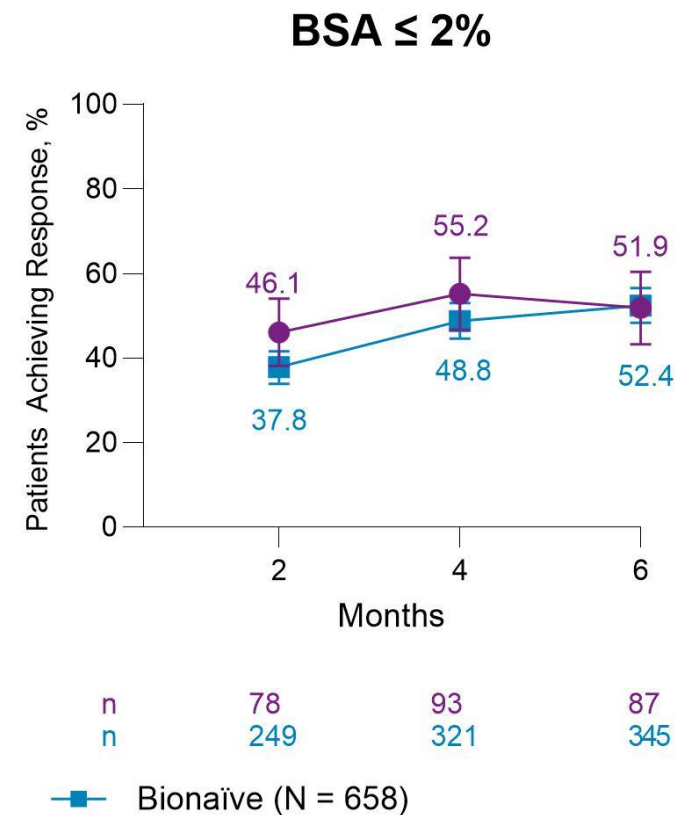
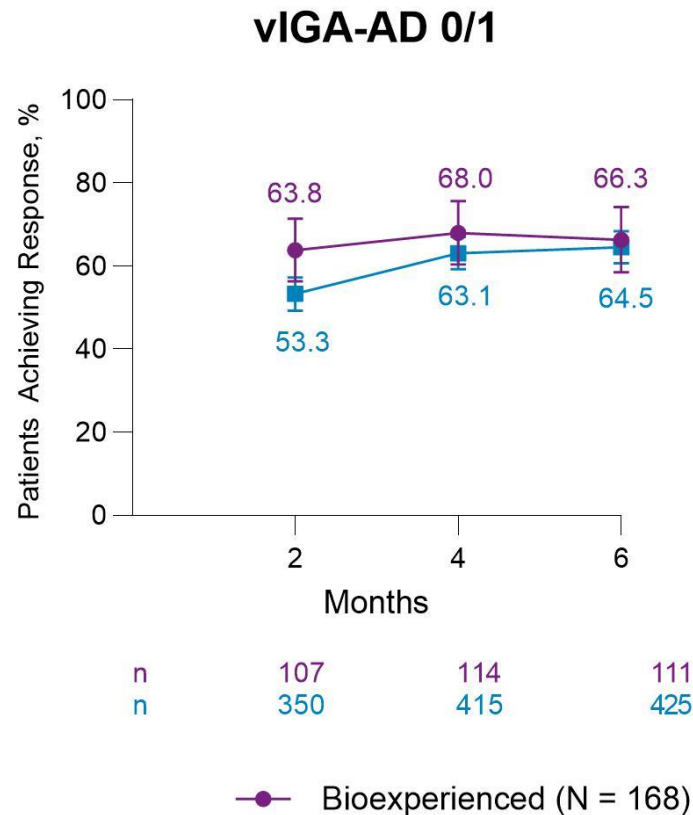
Demographic and Baseline Disease Characteristics by Starting Dose

| | Bioexperienced (BE) | | Bionaïve (BN) | |
|---|-------------------------------|-------------------------------|--------------------------------|--------------------------------|
| | Started on UPA 15 mg (N = 84) | Started on UPA 30 mg (N = 92) | Started on UPA 15 mg (N = 381) | Started on UPA 30 mg (N = 299) |
| Age, years, mean (SD) | 36.2 (17.2) | 36.0 (13.5) | 37.1 (19.1) | 36.3 (13.4) |
| Male, n (%) | 52 (61.9) | 52 (56.5) | 196 (51.4) | 180 (60.2) |
| Duration of AD symptoms, years, mean (SD) | 26.4 (15.2) | 30.6 (15.1) | 22.3 (15.2) | 25.1 (14.8) |
| Comorbidities, n (%) | | | | |
| <i>Asthma</i> | 27 (32.1) | 43 (46.7) | 89 (23.4) | 95 (31.8) |
| <i>Allergic rhinitis</i> | 39 (46.4) | 45 (48.9) | 111 (29.1) | 88 (29.4) |
| vIGA-AD - n (%) | | | | |
| <i>Moderate (3)</i> | 47 (56.6) | 46 (51.1) | 181 (48.3) | 132 (44.4) |
| <i>Severe (4)</i> | 28 (33.7) | 37 (41.1) | 164 (43.7) | 152 (51.2) |
| EASI total score, mean (SD) | 19.3 (11.2) | 20.5 (10.4) | 22.4 (12.0) | 23.5 (11.9) |
| EASI body region scores, median (range) | | | | |
| <i>Head and Neck</i> | 1.8 (0.0, 6.6) | 2.2 (0.0, 6.0) | 2.0 (0.0, 7.2) | 1.8 (0.0, 7.2) |
| <i>Trunk</i> | 4.8 (0.0, 18.0) | 6.2 (0.0, 19.8) | 6.3 (0.0, 21.6) | 6.3 (0.0, 21.6) |
| <i>Upper limbs</i> | 4.0 (0.0, 13.2) | 4.2 (0.0, 12.0) | 4.8 (0.0, 14.4) | 4.8 (0.0, 14.4) |
| <i>Lower limbs</i> | 7.2 (0.0, 24.0) | 7.2 (0.0, 22.0) | 8.4 (0.0, 28.8) | 9.2 (0.0, 26.4) |
| Body surface area, %, mean (SD) | 29.3 (20.8) | 36.8 (22.9) | 36.8 (23.8) | 39.4 (23.7) |
| PROs, mean (SD) | | | | |
| <i>WP-NRS</i> | 6.1 (2.6) | 6.4 (2.3) | 7.3 (2.2) | 7.3 (2.2) |
| <i>POEM</i> | 15.5 (6.5) | 17.2 (6.5) | 18.4 (6.6) | 19.6 (6.3) |
| <i>DLQI</i> | 12.5 (7.7) | 13.2 (7.1) | 14.6 (7.0) | 15.4 (7.1) |
| <i>ADCT</i> | 13.2 (5.9) | 13.2 (6.2) | 15.7 (5.7) | 15.8 (5.5) |

- The analysis included 176 BE and 680 BN patients, with 6.3% and 9.4% of adolescents in each group, respectively
- Baseline characteristics were generally similar for both treatment groups
 - BE patients generally experienced less severe disease (eg, BSA, EASI score, vIGA-AD) and were more likely to have asthma and allergic rhinitis vs BN patients
- In both groups, patients started on UPA 15 mg in an attempt to use the lowest possible dose
- Patients started on UPA 30 mg:
 - **BN group:** mainly for skin severity (42.2%), itch (21.1%), and lack of effectiveness of prior therapies (17.5%)
 - **BE group:** reasons included skin severity (29.1%), itch (19.0%), lack of effectiveness of prior therapies (17.7%), lesion location (12.7%), and other disease burden factors (10.1%)
- **Prior biologic therapy usage among patients (≥5%)** in the BE group consisted mainly of dupilumab (n = 155; 88.1%) and tralokinumab (n = 25; 14.2%)

Achievement of vIGA-AD 0/1 and BSA at Months 2, 4, and 6

- At baseline, only 2.3 and 1.2% of BE/BN patients, respectively, had a vIGA-AD 0/1
- Most BE and BN patients achieved vIGA-AD 0/1, and over 37% had BSA $\leq 2\%$ at month 2
 - Achievement rates increased by month 4 and were generally maintained by month 6



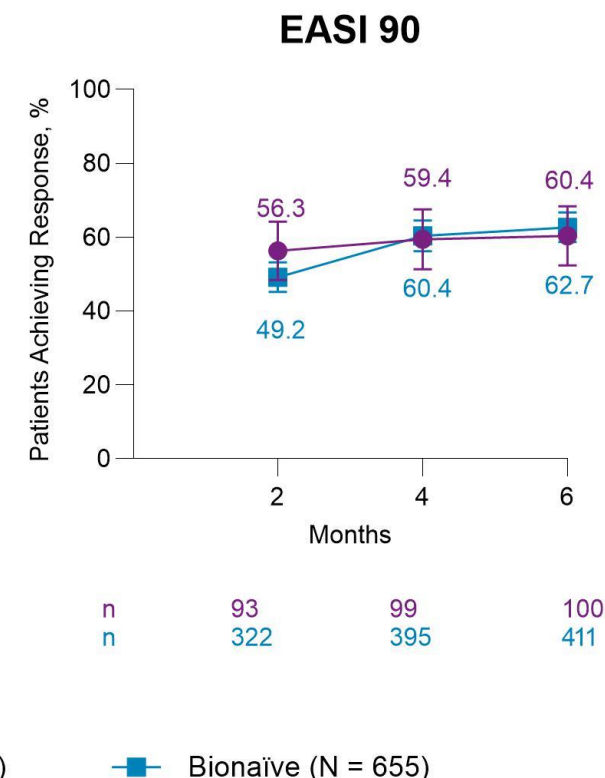
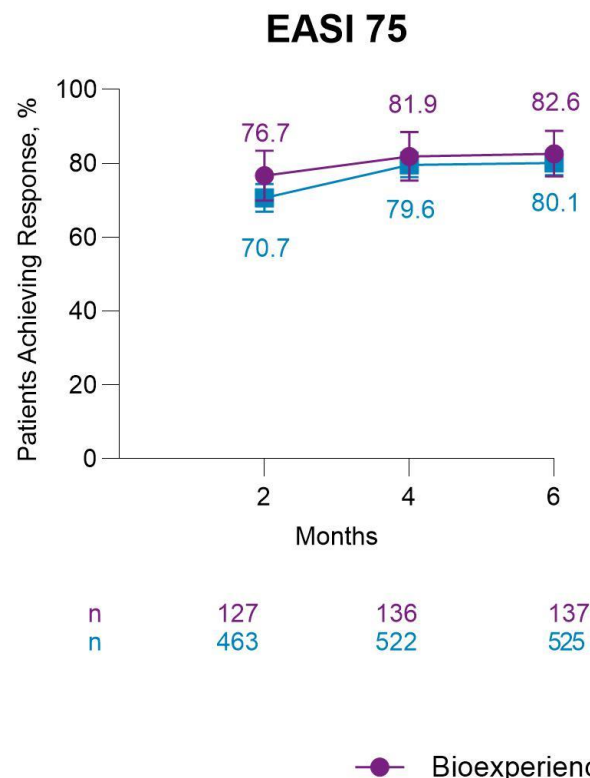
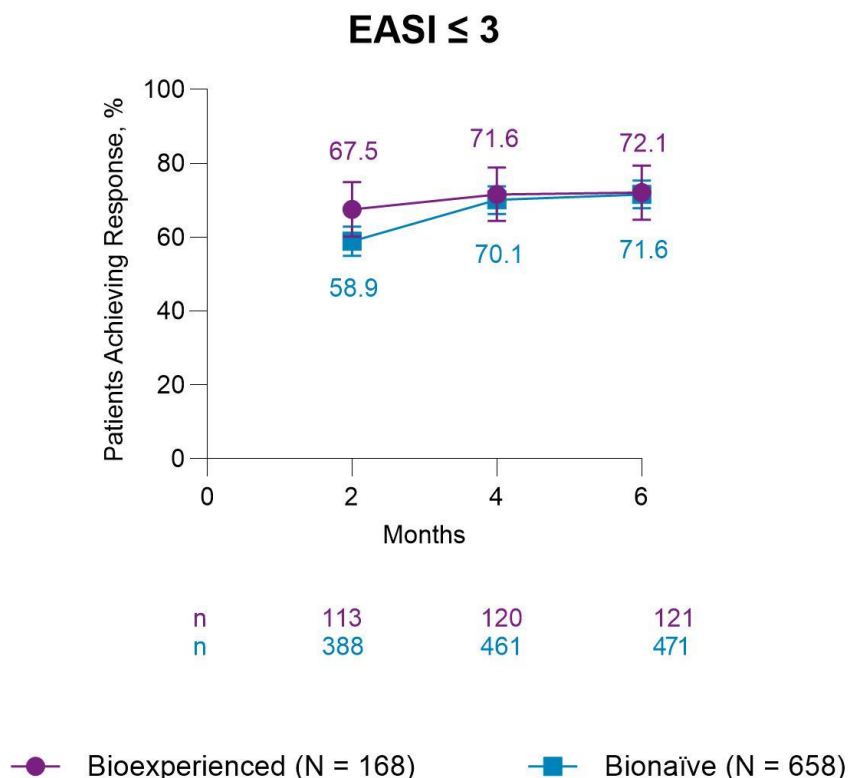
Error bars correspond to the 95% confidence interval for response rate.

Results are based on non-responder imputation with multiple imputation (NRI-MI).

BE, bioexperienced; BN, bionäive; BSA, body surface area; vIGA-AD, validated Investigator Global Assessment for Atopic Dermatitis.

Achievement of EASI 75, EASI 90, and EASI ≤ 3 at Months 2, 4, and 6

- Both BE and BN patients achieved similar and high response rates across all EASI endpoints (EASI 75, EASI 90, EASI ≤ 3), with improvement over time



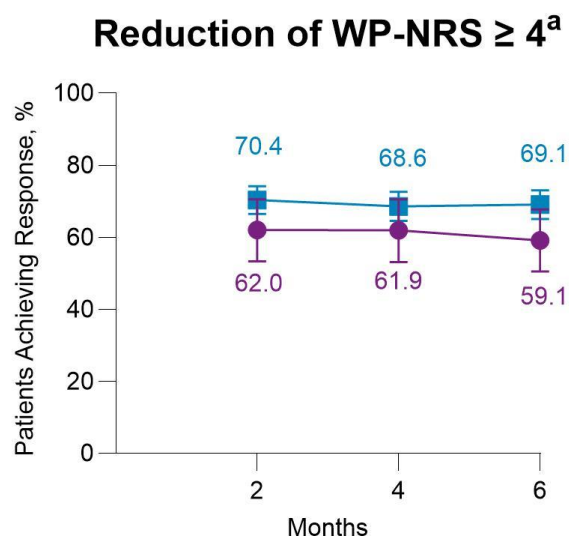
Error bars correspond to the 95% confidence interval for response rate.

Results are based on non-responder imputation with multiple imputation (NRI-MI).

BE, bioexperienced; BN, bionaïve; EASI 75/90, 75%/90% reduction in baseline Eczema Area and Severity Index score.

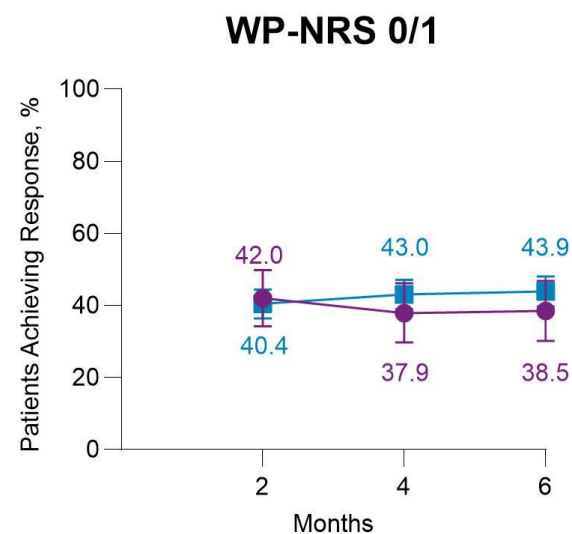
Achievement of Stringent Itch and Combined Stringent Itch and Skin Clearance (Minimal Disease Activity) Outcome Measures at Months 2, 4, and 6

- Numerically more BN than BE patients reported clinically relevant itch improvements, while response rates for little-to-no itch (WP-NRS 0/1) and the simultaneous achievement of little-to-no itch and almost clear skin (EASI \leq 3 + WP-NRS 0/1), a definition of Minimal Disease Activity,¹ were consistent over the study period and similar between the 2 groups



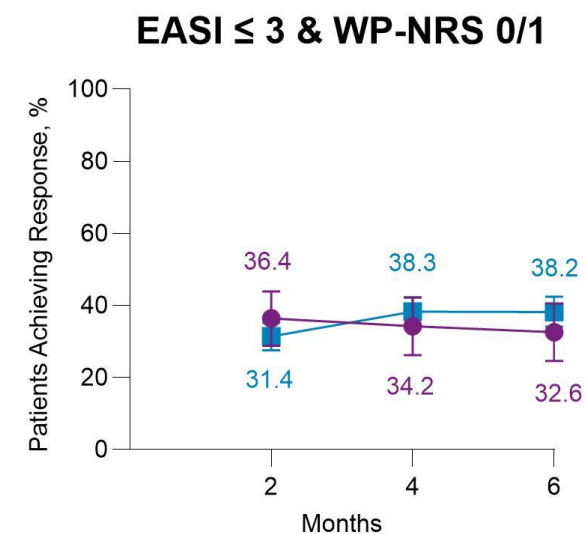
n
n

| | | |
|-----|-----|-----|
| 88 | 88 | 84 |
| 430 | 419 | 422 |



n
n

| | | |
|-----|-----|-----|
| 71 | 64 | 65 |
| 266 | 283 | 289 |



n
n

| | | |
|-----|-----|-----|
| 61 | 57 | 55 |
| 207 | 252 | 252 |

● Bioexperienced (N = 142) ■ Bionaire (N = 611)

● Bioexperienced (N = 168) ■ Bionaire (N = 658)

Error bars correspond to the 95% confidence interval for response rate. Results are based on non-responder imputation with multiple imputation (NRI-MI).

^aAmong patients with baseline WP-NRS \geq 4.

1. Silverberg JI, et al. *J Eur Acad Dermatol Venereol*. 2024;38(11):2139-2148.

BE, bioexperienced; BN, bionaire; EASI, Eczema Area and Severity Index score; WP-NRS, Worst Pruritus – Numerical Rating Scale.

Achievement of Stringent Quality of Life, Symptom Relief, and Disease Control Outcome Measures at Months 2, 4, and 6

- In both BE and BN populations, more than 74% achieved meaningful improvements in QoL ($\Delta\text{DLQI} \geq 4$), symptom relief ($\Delta\text{POEM} \geq 4$), and disease control ($\Delta\text{ADCT} \geq 5$) at months 2, 4, and 6
- Over 71% of patients in the BN and BE populations achieved ADCT scores < 7 through month 6, indicating well-controlled AD symptoms
- More stringent outcomes of DLQI 0/1 (no impact on QoL) and POEM ≤ 2 (clear/almost clear eczema) were achieved by 35% of patients or more in both groups at months 2, 4, and 6

DLQI, POEM, and ADCT Outcomes

| Outcome Measures | Bioexperienced Any UPA, n/N (%) | | | Bionaïve Any UPA, n/N (%) | | |
|---|------------------------------------|----------------|----------------|------------------------------|----------------|----------------|
| | Month 2 | Month 4 | Month 6 | Month 2 | Month 4 | Month 6 |
| DLQI 0/1 ^a | 64/163 (39.4) | 61/163 (37.4) | 63/163 (38.5) | 230/627 (36.7) | 266/627 (42.5) | 263/627 (42.0) |
| DLQI ≥ 4 -point reduction from BL ^b | 109/147 (74.4) | 117/147 (79.5) | 121/147 (82.6) | 504/591 (85.2) | 513/591 (86.7) | 513/591 (86.8) |
| POEM ≤ 2 | 61/168 (36.3) | 56/168 (33.6) | 59/168 (35.1) | 235/658 (35.8) | 243/658 (37.0) | 258/658 (39.2) |
| POEM ≥ 4 -point reduction from BL ^c | 135/163 (82.7) | 131/163 (80.8) | 131/163 (80.4) | 559/645 (86.7) | 548/645 (84.9) | 550/645 (85.3) |
| ADCT < 7 | 122/168 (72.8) | 120/168 (71.4) | 121/168 (71.8) | 483/658 (73.4) | 483/658 (73.5) | 482/658 (73.3) |
| ADCT ≥ 5 -point reduction from BL ^d | 119/154 (77.8) | 118/154 (76.6) | 124/154 (80.4) | 525/632 (83.1) | 517/632 (81.9) | 515/632 (81.5) |

^aAmong patients ≥ 16 years old; ^bAmong patients ≥ 16 years old with baseline DLQI ≥ 4 ; ^cAmong patients with baseline POEM ≥ 4 ; ^dAmong patients with baseline ADCT ≥ 5 .

AD, atopic dermatitis; ADCT, Atopic Dermatitis Control Tool; BE, bioexperienced; BL, baseline; BN, bionaïve; DLQI, Dermatology Life Quality Index; POEM, Patient Oriented Eczema Measurement; QoL, quality of life; UPA, upadacitinib. Results are based on non-responder imputation with multiple imputation (NRI-MI).

CONCLUSIONS

Compared to bionative patients, bioexperienced patients generally presented with less severe disease, and started on UPA 30 mg for more varied reasons, including the anatomical location of lesions

Regardless of prior biologic therapy exposure, real-world patients with atopic dermatitis treated with upadacitinib achieved high rates of skin clearance and itch relief, with about one third simultaneously achieving little-to-no itch and almost clear skin, up to month 6

Bionative and bioexperienced patients experienced meaningful improvements in quality of life, symptom relief, and disease control, with consistent outcomes observed in both groups



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