Real-World Use and Effectiveness of Upadacitinib in Australians aged ≥12 years With Atopic Dermatitis: 6-month Interim Analysis of the Real-World AD-VISE Study

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Author’s data, co-authors’ data and affiliations

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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)[1-3]
- AD-VISE (NCT05081557) is an ongoing observational, prospective, multi-country 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 years[1]
- Australian real-world data is scarce for UPA treatment in patients with moderate-to-severe AD.

Objective

- Evaluate effectiveness of UPA for AD in Australian real-world clinical practice and describe the Australian AD-VISE population.

AD, atopic dermatitis; UPA, upadacitinib.

1. RINVOQ® (upadacitinib) Australian Product Information. **2**. Silverberg JI *et al. J Allergy Clin Immunol* 2022;149:977–87. e14. **3**. Simpson EL *et al. JAMA Dermatol* 2022;158:404–13.

Methods

Data Source & Patient population:

- AD-VISE is an ongoing observational, prospective, multi-country study of patients aged ≥12 years who were prescribed UPA for AD before study entry.[1]
- Effectiveness results include N=45 Australian patients with at least 6 months of enrolment as of the 16Jan2025 cutoff date and patients that discontinued from the study prior to having 6 months enrolment.

Outcomes and Data Analysis:

- Outcome measures included:
  - **Primary, vIGA-AD 0/1** Validated Investigator Global Assessment for AD 0/1
  - **EASI** Eczema Area and Severity Index
  - **WP-NRS** Worst Pruritus Numerical Rating Scale
  - **DLQI** Dermatology Life Quality Index
  - **POEM** Patient Oriented Eczema Measurement
  - **PGIT-AD** Patient Global Impression of Treatment for Atopic Dermatitis
  - **ADCT** Atopic Dermatitis Control Tool
- Achievement of **Minimal Disease Activity** was defined as the simultaneous achievement of **EASI score ≤3 and WP-NRS 0 or 1.4**.
- Effectiveness results are based on non-responder imputation with multiple imputation (NRI-MI). Subjects who discontinue UPA due to lack of efficacy, no longer clinically benefitting, or an adverse event with possible relationship to UPA are coded as non-responders. Multiple imputation is used for assessments after UPA discontinuation due to other reasons and missing assessments while treated with UPA.

1. A Study to Assess Real-World Use, Safety, and Effectiveness of Oral Upadacitinib in Adult and Adolescent (≥12 Years Old) Participants With Atopic Dermatitis (AD-VISE). Clinicaltrials.gov NCT05081557. Available at https://www.clinicaltrials.gov/study/NCT05081557.

Baseline patient clinical and demographic characteristics

At baseline:

- 93.6% were adults
- 76.6% initiated UPA at 15 mg
- Mean BSA was 27.5%
- Arm, leg and anterior trunk were the most commonly affected sites (≥90%)

	UPA 15 mg QD (N=36)	UPA 30 mg QD (N=11)	Any UPA (N=47)
Age (year) n (%)			
<18	2 (5.6)	1 (9.1)	3 (6.4)
18 to <40	19 (52.8)	6 (54.5)	25 (53.2)
40 to <65	13 (36.1)	3 (27.3)	16 (34.0)
≥65	2 (5.6)	1 (9.1)	3 (6.4)
Female, n (%)	23 (63.9)	6 (54.5)	29 (61.7)
Duration of AD symptoms (years)			
Mean (SD)	26.2 (15.7)	37.3 (10.5)	28.8 (15.3)
Median	23.0	37.0	27.0
Disease-related co-morbidities, n (%)			
Asthma	10 (27.8)	9 (81.8)	19 (40.4)
Allergic rhinitis	14 (38.9)	8 (72.7)	22 (46.8)
Food allergies	9 (25.0)	1 (9.1)	10 (21.3)
AD location, n (%)	[N=33]	[N=7]	[N=40]
Face	25 (75.8)	4 (57.1)	29 (72.5)
Neck	27 (81.8)	5 (71.4)	32 (80.0)
Scalp	16 (48.5)	3 (42.9)	19 (47.5)
Arm	32 (97.0)	7 (100)	39 (97.5)
Hand	26 (78.8)	5 (71.4)	31 (77.5)
Leg	30 (90.9)	6 (85.7)	36 (90.0)
Foot	17 (51.5)	2 (28.6)	19 (47.5)
Anterior trunk	31 (93.9)	7 (100)	38 (95.0)
Posterior trunk	29 (87.9)	4 (57.1)	33 (82.5)
Genitalia	8 (24.2)	0	8 (20.0)
Body surface area, % mean (SD)	48.8 (26.7) [N=33]	23.3 (22.6) [N=7]	44.3 (27.5) [N=40]
Prurigo nodules, n (%)	14 (38.9)	2 (18.2)	16 (34.0)
Prior dupilumab use (any indication), n (%)	4 (11.1)	5 (45.5)	9 (19.1)
Prior non-biologic immunomodulating systemic therapy for AD, n (%)	5 (13.9)	2 (18.2)	7 (14.9)

AD, atopic dermatitis; ADCT, Atopic Dermatitis Control Tool; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; POEM, Patient Oriented Eczema Measurement; vIGA-AD, Validated Investigator Global Assessment for Atopic Dermatitis; WP-NRS, Worst Pruritus Numeric Rating Scale. If a different N was used for an assessment, the actual N is presented in square brackets [N].

Baseline patient clinical and demographic characteristics cont'd

At baseline:

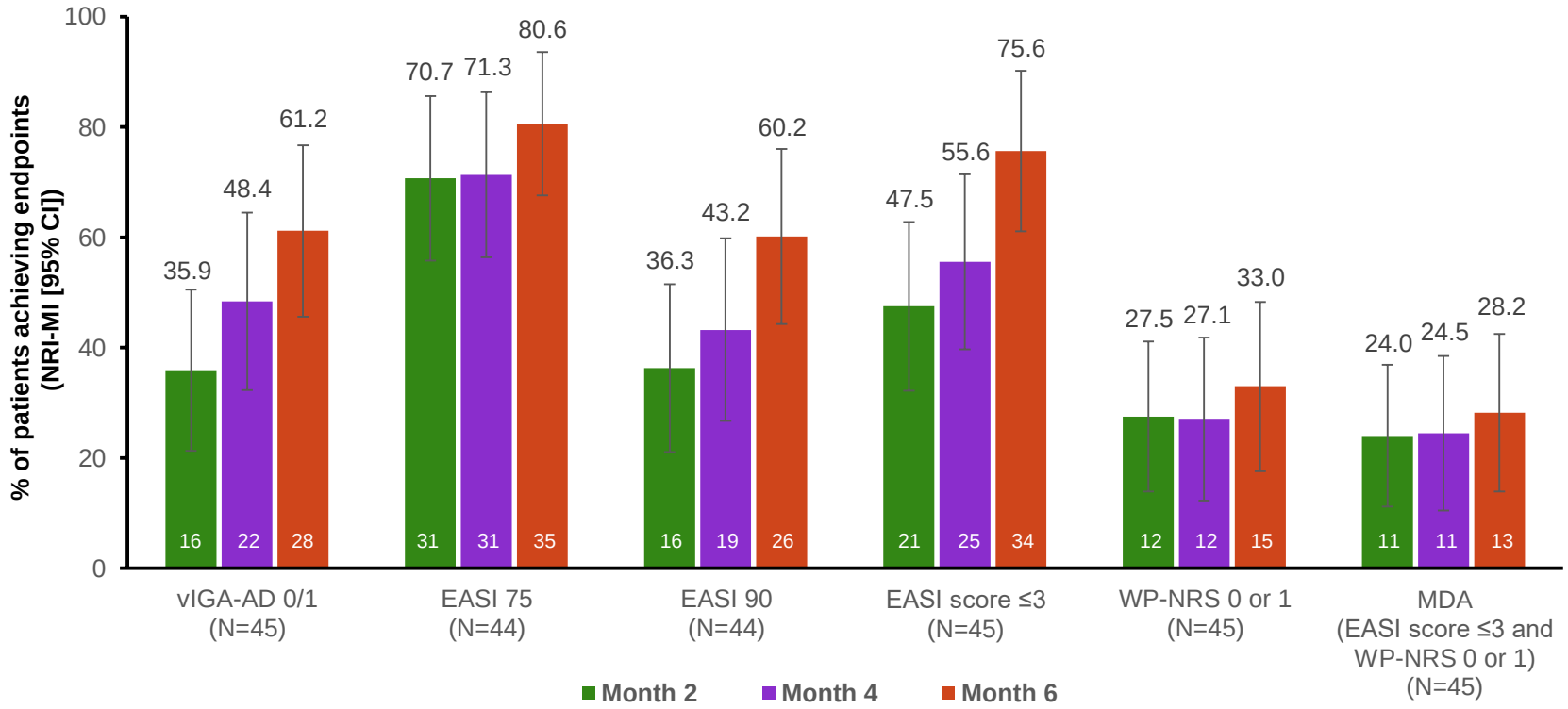
- 90.0% had vIGA-AD Moderate (3) or Severe (4)
- 82.1% were experiencing a current flare, and 92.3% had experienced a flare in the last 6 months
- 46.2% were either somewhat, very, or extremely dissatisfied with their current treatment according to PGIT-AD

	UPA 15 mg QD (N=36)	UPA 30 mg QD (N=11)	Any UPA (N=47)
Current AD flare, n (%)	[N=32]	[N=7]	[N=39]
Yes	26 (81.3)	6 (85.7)	32 (82.1)
No	5 (15.6)	0	5 (12.8)
Don't know	1 (3.1)	1 (14.3)	2 (5.1)
AD flare in the last 6 months, n (%)	[N=32]	[N=7]	[N=39]
Yes	30 (93.8)	6 (85.7)	36 (92.3)
No	1 (3.1)	0	1 (2.6)
Don't know	1 (3.1)	1 (14.3)	2 (5.1)
vIGA-AD, n (%)	[N=33]	[N=7]	[N=40]
0 (Clear)	0	0	0
1 (Almost clear)	1 (3.0)	0	1 (2.5)
2 (Mild)	0	3 (42.9)	3 (7.5)
3 (Moderate)	12 (36.4)	2 (28.6)	14 (35.0)
4 (Severe)	20 (60.6)	2 (28.6)	22 (55.0)
PGIT-AD, n (%)	[N=32]	[N=7]	[N=39]
Extremely or Very dissatisfied	8 (25)	1 (14.3)	9 (23.1)
Somewhat dissatisfied	7 (21.9)	2 (28.6)	9 (23.1)
Neither dissatisfied nor satisfied	7 (21.9)	1 (14.3)	8 (20.5)
Somewhat satisfied	7 (21.9)	3 (42.9)	10 (25.6)
Extremely or Very satisfied	3 (9.4)	0	3 (7.7)
EASI, mean (SD)	24.7 (12.55) [N=33]	16.2 (11.38) [N=7]	23.2 (12.64) [N=40]
WP-NRS, mean (SD)	7.2 (2.08) [N=31]	6.9 (2.97) [N=7]	7.1 (2.23) [N=38]
DLQI, mean (SD) *[Assessed in patients aged ≥16 years]*	16.0 (7.39) [N=24]	19.4 (7.40) [N=5]	16.6 (7.38) [N=29]
POEM, mean (SD)	19.1 (6.45) [N=31]	20.9 (5.70) [N=7]	19.4 (6.28) [N=38]
ADCT, mean (SD)	16.6 (5.42) [N=32]	16.0 (6.56) [N=7]	16.5 (5.55) [N=39]

AD, atopic dermatitis; ADCT, Atopic Dermatitis Control Tool; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; POEM, Patient Oriented Eczema Measurement; vIGA-AD, Validated Investigator Global Assessment for Atopic Dermatitis; WP-NRS, Worst Pruritus Numeric Rating Scale. If a different N was used for an assessment, the actual N is presented in square brackets [N].

Results: Effectiveness of UPA on clinician and patient-reported outcomes at Months 2, 4 and 6

- Rates of vIGA-AD 0/1 increased from 2.5% (n=1/40) at baseline to 35.9%, 48.4% and 61.2%, at Months 2, 4 (co-primary outcome) and 6, respectively.
- By Month 6, most patients had achieved either a 75% or 90% improvement in EASI score (EASI 75, 80.6%; EASI 90, 60.2%).
- Simultaneous achievement of EASI score ≤3 and WP-NRS 0 or 1, which indicates minimal disease activity (MDA), was attained by 28.2% of patients at Month 6.

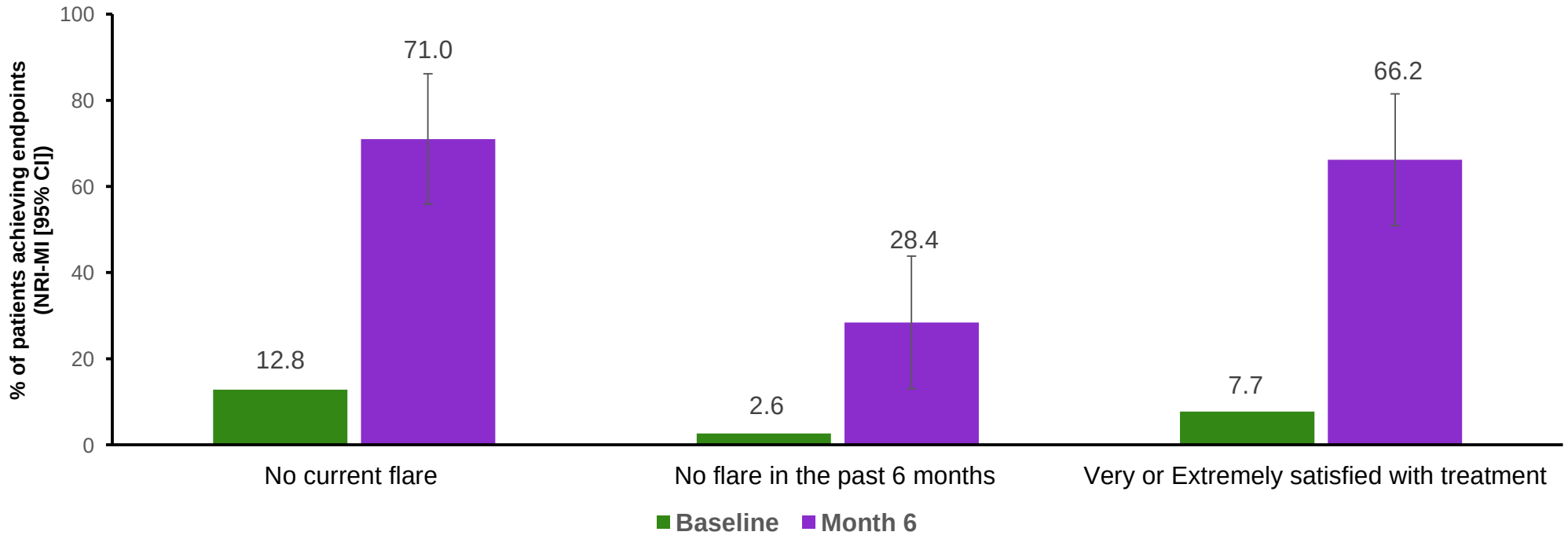


Numbers at the bottom of each bar represent n.

AD, atopic dermatitis; CI, confidence interval; EASI, Eczema Area and Severity Index; MDA, Minimal disease activity (composite score); NRI-MI, non-responder imputation with multiple imputation; vIGA-AD, Validated Investigator Global Assessment for Atopic Dermatitis; WP-NRS, Worst Pruritus Numeric Rating Scale.

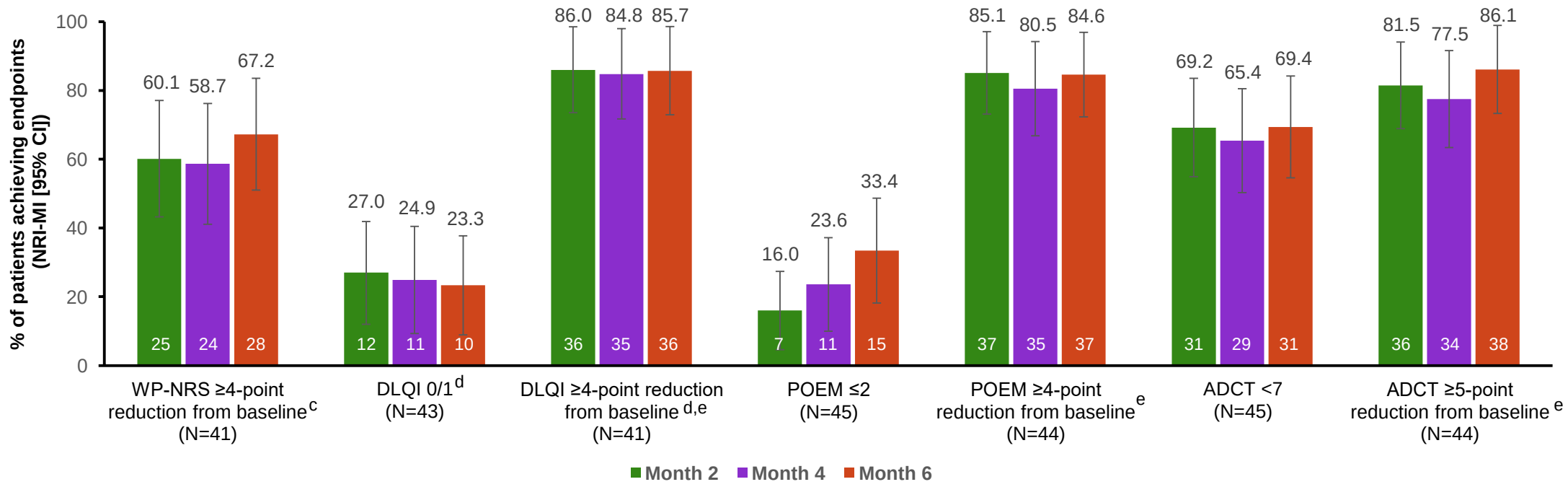
Results: Effectiveness of UPA on flares and patient satisfaction with treatment

- Rates of No Current Flare increased from 12.8% (n=5/39) at baseline to 71.0% (N=42) at Month 6.
- Rates of No Flare in the Past 6 Months increased from 2.6% (n=1/39) at baseline to 28.4% (N=41) at Month 6.
- The proportion of patients who reported being Very or Extremely Satisfied with treatment using the PGIT-AD increased from only 7.7% (n=3/39) at baseline, to 66.2% at Month 6 (N=45).



Results: Effectiveness of UPA on patient-reported outcomes at Months 2, 4 and 6

- Clinically meaningful improvements were also seen across all of the assessed patient-reported outcomes
- At 6 months of UPA treatment, ~85% of patients achieved clinically significant improvements in disease control (ADCT), symptoms (POEM) and quality of life (DLQI).



Numbers at the bottom of each bar represent n. [c]Baseline score ≥4. [d]DLQI was assessed in patients aged ≥16 years. [e]Baseline score ≥5.

ADCT, Atopic Dermatitis Control Tool; DLQI, Dermatology Life Quality Index; POEM, Patient Oriented Eczema Measurement; WP-NRS, Worst Pruritus Numeric Rating Scale. Percentages are calculated based on non-missing values.

CONCLUSIONS

AD-VISE (NCT05081557) is an ongoing, observational, multi-country study of patients receiving UPA for moderate-to-severe AD, designed to evaluate utilisation patterns and effectiveness per the local label.

After 6 months of treatment with UPA for AD, the majority of Australian patients achieved vIGA-AD 0/1, EASI 75 and EASI 90; as well as improvements in disease control, symptoms and quality of life. Around one-third of patients achieved the stringent target of Minimal Disease Activity (MDA), defined as simultaneous EASI ≤3 and WP-NRS 0/1.

This is the initial readout from the first prospective study documenting the real-world of effectiveness of UPA in Australian patients with AD. Despite the small Australian population in these analyses, these outcomes were in line with those from international UPA AD trials.

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