

Impact of Achieving and Maintaining Minimal Disease Activity on Long-Term Patient-Reported Outcomes in Patients with Moderate-to-Severe Atopic Dermatitis: Post-hoc Analysis from Measure Up 1 and 2

Tiago Torres^{1,2}, Vimal H. Prajapati^{3,6}, Laura Savage⁷, Masatoshi Abe⁸, Simone Riberio⁹, Richard Ta¹⁰, Chao Li¹⁰, Ayman Grada¹⁰, Meerat Oza¹⁰, Wan-Ju Lee¹⁰, Christopher G. Bunick¹¹

¹Department of Dermatology, Clinical Academic Centre-IGBAS/Santo António, Porto, Portugal; ²Instituto de Ciências Biomédicas Abel Salazar, University of Porto, Porto, Portugal; ³Skin Health & Wellness Centre and Dermatology Research Institute, Calgary, Alberta, Canada; ⁴Probit Medical Research, Calgary, Alberta, Canada; ⁵Division of Dermatology, Department of Medicine, University of Calgary, Calgary, Alberta, Canada; ⁶Sections of Community Pediatrics and Pediatric Rheumatology, Department of Pediatrics, University of Calgary, Calgary, Alberta, Canada; ⁷Leeds Centre for Dermatology, Faculty of Medicine and Health, University of Leeds, Leeds, United Kingdom; ⁸Kojinkai Sapporo Skin Clinic, Sapporo, Japan; ⁹Department of Medical Sciences, Section of Dermatology, University of Turin, Turin, Italy; ¹⁰AbbVie Inc., North Chicago, Illinois, United States; ¹¹Department of Dermatology and Program in Translational Biomedicine, Yale School of Medicine, New Haven, Connecticut, United States

OBJECTIVE

To assess the impact of achieving and maintaining minimal disease activity (MDA) on long-term patient benefit in moderate-to-severe atopic dermatitis (AD)

CONCLUSIONS

In moderate-to-severe AD, more patients who achieved MDA at week 16 attained long-term optimal patient-reported outcomes (PROs) at week 140 compared with patients who achieved moderate targets at week 16

Patients who achieved and maintained MDA in ≥80% of study visits between week 16 and week 140 had the greatest achievement of optimal patient outcomes across quality of life, sleep, disease severity, and skin pain

Achieving and maintaining MDA was associated with incremental benefit in long-term PROs across multiple dimensions of health in patients with moderate-to-severe AD

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SYNOPSIS

- AD is characterized by an intense itch and recurrent flares with typical eczematous morphology that have multidimensional impacts on daily activities, sleep patterns, and overall quality of life¹
- Standard of care in AD continues to evolve as more advanced therapies become available²
- The AHEAD (Aiming High in Eczema/Atopic Dermatitis) recommendations outlined optimal treatment targets for clinician-reported outcomes (ClinROs) and patient-reported outcomes (PROs) and defined Minimal Disease Activity (MDA) as achievement of optimal targets on ≥1 ClinRO and ≥1 PRO³
- We evaluated the impact of achieving and maintaining MDA on long-term PROs in patients with moderate-to-severe AD using MEASURE UP 1 and MEASURE UP 2 studies

METHODS

- MEASURE UP 1 (NCT03569293) and MEASURE UP 2 (NCT03607422) were replicate, multicenter, phase 3 clinical trials that evaluated once-daily orally-administered upadacitinib (UPA) monotherapy²
- This post-hoc analysis integrated data from MEASURE UP 1 and 2; patients from 2 UPA treatment (15 mg and 30 mg) and placebo arms were pooled (Figure 1)
- At week 16, 2 mutually exclusive patient groups were identified using skin and itch target achievement based on AHEAD recommendations (Table 1)³
- Among patients who achieved MDA at week 16, 3 cohorts were identified based on the maintenance of MDA at a total of 13 study visits between week 16 and week 140 (Table 2)
- Optimal PROs at week 140 (Table 3) were examined between MDA vs Moderate-Target groups, as well as across 3 cohorts by level of MDA maintenance
- Response rates were reported based on observed cases (OC)

RESULTS

- More patients who achieved MDA (n=380) at week 16 attained optimal PROs at week 140 compared with patients who achieved moderate targets (n=232) across the Dermatology Quality of Life Index/Children's Dermatology Life Quality Index (DLQI/CDLQI) 0/1, Sleep Numerical Rating Scale (NRS) 0/1, Patient-Oriented Eczema Measure (POEM) 0–2, Skin Pain NRS 0/1, Atopic Dermatitis Impact Scale (ADerm-IS) Daily Activities 0-2, and ADerm-IS Emotional State 0-2 (Figure 2)
- Among MDA achievers at week 16, the majority (n=238, 62.6%) maintained MDA status at ≥ 50% of study visits, and 37.9% (n=144) maintained MDA at ≥80% of study visits through week 140 (Figure 3)
- Among MDA achievers at week 16, patients who achieved and maintained MDA in ≥80% of study visits through week 140 (n=144) reported the highest proportion of DLQI/CDLQI 0/1, Sleep NRS 0/1, POEM 0–2, Skin Pain NRS 0/1, ADerm-IS Daily Activities 0-2, and ADerm-IS Emotional State 0-2 (Figure 4)

Figure 2. Achievement of Optimal PROs at Week 140 by MDA (Optimal Target) vs Moderate-Target Group at Week 16

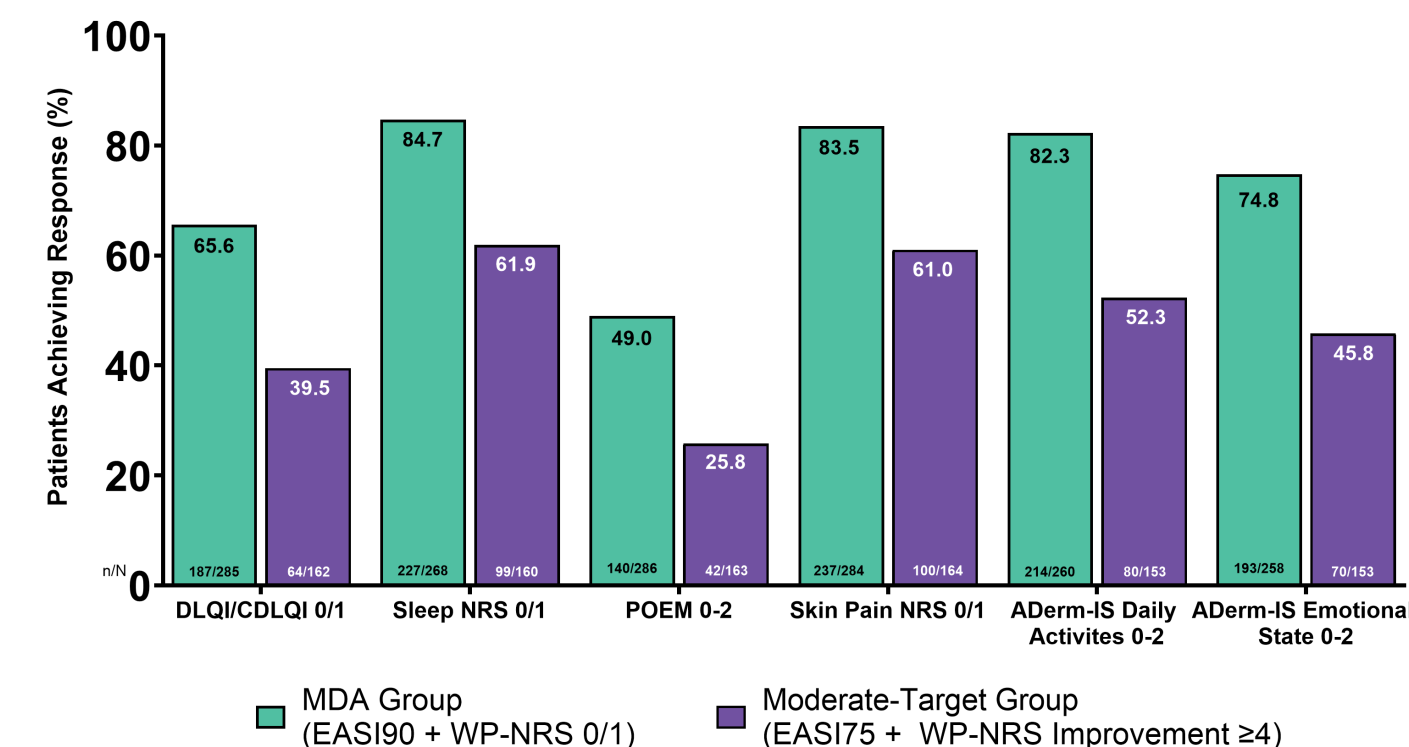
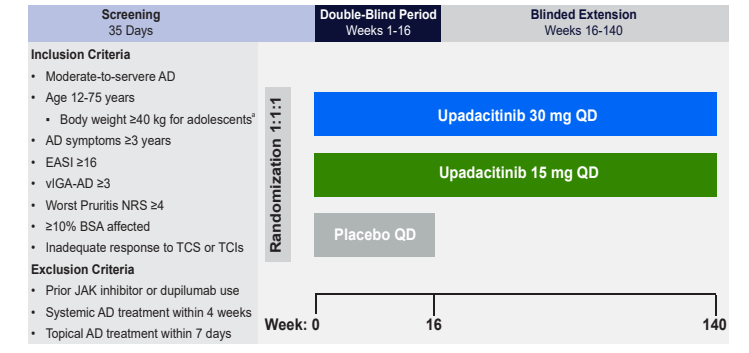


Table 1. Definition of MDA (Optimal Target) and Moderate-Target Groups at Week 16

| Group | Definition |
|-----------------------|--|
| MDA Group | Patients achieved both EASI90 and WP-NRS 0/1 (optimal target) |
| Moderate-Target Group | Patients achieved both EASI75 and WP-NRS improvement ≥4 points |

Missing EASI and WP-NRS scores were not imputed (OC). Patients in MDA and Moderate-Target groups are mutually exclusive.
 Abbreviations: EASI, Eczema Area and Severity Index; EASI 75/90, ≥75%/≥90% improvement from baseline; WP-NRS, Worst Pruritus Numerical Rating Scale.

Figure 1. Study Design of Measure Up 1 and Measure Up 2 Studies



*Aged <18 years.
 Abbreviations: BSA, body surface area; JAK, Janus kinase; NRS, Numerical Rating Scale; OC, once daily; TCI, topical calcineurin inhibitor; TCS, topical corticosteroids; vIGA-AD, validated Investigator Global Assessment for Atopic Dermatitis.

Table 2. Definition of MDA Maintenance Status Between Week 16 and Week 140

| Cohort | Definition |
|----------|--|
| Cohort 1 | Patients who achieved EASI90 and WP-NRS 0/1 at ≥80% of study visits (11 to 13 visits) |
| Cohort 2 | Patients who achieved EASI90 and WP-NRS 0/1 at 50-79% of study visits (7 to 10 visits) |
| Cohort 3 | Patients who achieved EASI90 and WP-NRS 0/1 at <50% of study visits (1 to 6 visits) |

Missing EASI and WP-NRS scores were not imputed (OC).

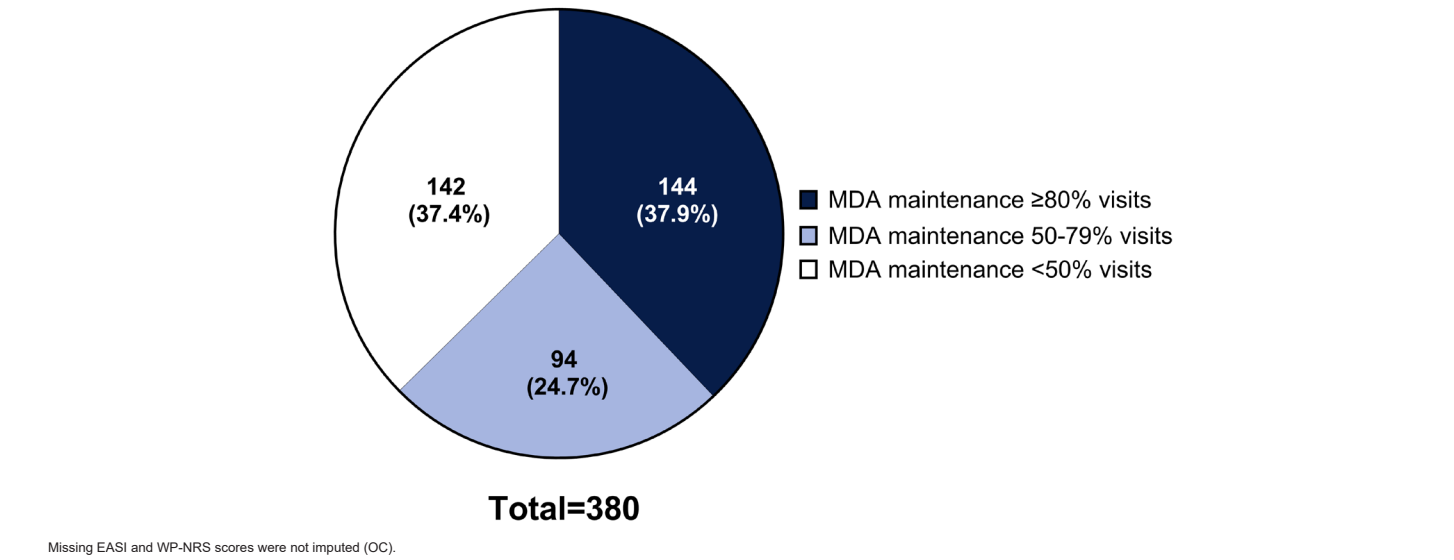
Table 3. Optimal Patient-Reported Outcomes at Week 140

| Category | Outcomes Definition | Interpretation |
|-----------------------|-------------------------------|---|
| Quality of life | DLQI/CDLQI 0/1 | No effect on patient's life |
| Sleep | Sleep NRS 0/1 | No or almost no impact on sleep disturbance |
| AD severity | POEM 0-2 | Clear or almost clear |
| Skin pain | Skin pain NRS 0/1 | No or almost no skin pain |
| Daily activity | ADerm-IS Daily Activities 0-2 | No or almost no impact on daily activities |
| Emotional functioning | ADerm-IS Emotional State 0-2 | No or almost no impact on emotional functioning |

Note: Sleep NRS is a single item from ADerm-IS about the impact of AD on sleep (0= not at all to 10= extremely). Skin pain NRS is a single item from ADerm-IS about the worst skin pain due to AD (0= no pain to 10= worst imaginable pain). Achievement of DLQI 0/1 is assessed among patients with DLQI >1 at baseline. Achievement of Sleep NRS 0/1 is assessed among patients with Sleep NRS >1 at baseline. Achievement of POEM 0-2 is assessed among patients with POEM >2 at baseline. Achievement of Skin pain NRS 0/1 is assessed among patients with Skin pain NRS >1 at baseline. Achievement of ADerm-IS Daily Activities 0-2 is assessed among patients with ADerm-IS Daily Activities >2 at baseline. Achievement of ADerm-IS Emotional State 0-2 is assessed among patients with ADerm-IS Emotional State >2 at baseline.

Abbreviations: ADerm-IS, Atopic Dermatitis Impact Scale; ADerm-SS, Atopic Dermatitis Symptom Scale; DLQI/CDLQI, Dermatology Life Quality Index/Children's DLQI; NRS, Numerical Rating Scale; POEM, Patient-Oriented Eczema Measure.

Figure 3. Distribution of MDA Maintenance Status Between Week 16 and Week 140



Missing EASI and WP-NRS scores were not imputed (OC).

Figure 4. Achievement of Optimal PROs at Week 140 in Groups Based on Maintenance of MDA Status

