# EFFICACY OF UPADACITINIB FOR MODERATE-TO-SEVERE ATOPIC DERMATITIS: ANALYSIS OF TIME SPENT IN SKIN CLEARANCE RESPONSE STATES FROM THE MEASURE UP 1, MEASURE UP 2, AND HEADS UP STUDIES

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## OBJECTIVE

To compare the time patients spent in skin clearance response states with upadacitinib 15 mg and 30 mg compared to placebo (over 16 weeks) and dupilumab (over 16 and 24 weeks)

**Patients treated with upadacitinib 15 mg or 30 mg compared to placebo spent more time at higher EASI response levels over 16 weeks, as did patients treated with upadacitinib 30 mg compared to dupilumab over 16 and 24 weeks.**

**On average, patients treated with upadacitinib spent approximately 10-13 times more days in EASI 90 compared to placebo.**

**On average, patients treated with upadacitinib 30 mg spent approximately 1.75-2.00 times more days in EASI 90 compared to dupilumab.**

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## INTRODUCTION AND METHODS

### Introduction

- Atopic dermatitis (AD) is a chronic, inflammatory skin disease characterized by intense pruritus. Symptoms can be debilitating, resulting in reductions to patient quality of life.
- Upadacitinib (UPA) is a selective oral Janus kinase (JAK) inhibitor approved to treat moderate-to-severe AD.
- Results from phase 3 and 3b trials indicated that UPA 30 mg and UPA 15 mg were superior to placebo (Measure Up 1, NCT03569293; Measure Up 2, NCT03607422) and UPA 30 mg was superior to dupilumab (DUPI: Heads Up, NCT03738397) in achieving Eczema Area and Severity Index (EASI) improvement of ≥75% from baseline at week 16.[1-4]
- The safety profile of UPA was consistent with previous AD studies, and the known safety profile of UPA across indications.[1,2]

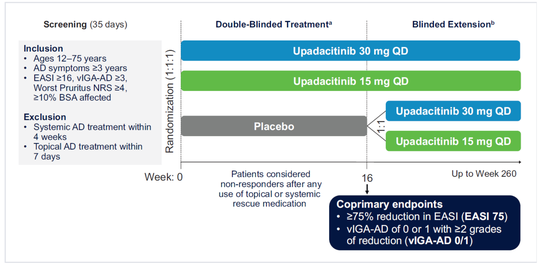
### Study Designs

- The Measure Up 1 and 2 studies were 16 week placebo-controlled phase 3 multicenter, randomized, double-blind studies with an ongoing blinded extension comparing the safety and efficacy of UPA 30 mg and UPA 15 mg to placebo in adults and adolescents with moderate-to-severe AD. (**Figure 1**)
- The Heads Up study was a 24-week head-to-head phase 3b multicenter, randomized, double-blind, double-dummy study comparing the safety and efficacy of UPA 30 mg to DUPI 300 mg in adults with moderate-to-severe AD. (**Figure 2**)

### Methods

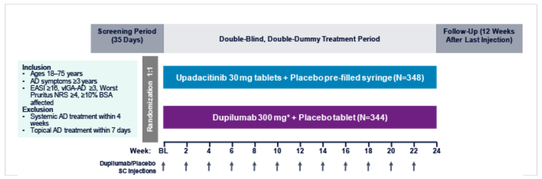
- The current study assessed the mean proportion and number of days patients spent in skin clearance response states based on improvements in EASI score of ≥75%/90%/100% (EASI 75/90/100) from baseline.
- Missing data at study visits were imputed using non-responder imputation (NRI). Response states between study visits were interpolated using last observation carried forward (LOCF).
- Classification of a response as EASI 100 indicated clear skin with no signs of AD. Classification of a response as EASI 90-<100 indicated a major clinical response with almost clear skin.

### Figure 1. Measure Up 1 & 2 Study Design




[a]Data reported here are from the double-blind treatment period.
[b]The blinded extension period is ongoing.
AD, atopic dermatitis; BSA, body surface area; EASI, Eczema Area and Severity Index; NRS, Numerical Rating Scale; QD, once daily; vIGA-AD, Validated Investigator's Global Assessment for AD.

### Figure 2. Heads Up Study Design

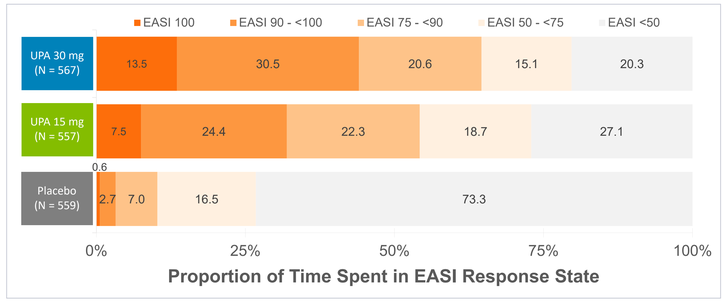



AD, Atopic Dermatitis; EASI, Eczema Area and Severity Index; vIGA-AD, Validated Investigator Global Assessment scale for Atopic Dermatitis; Worst Pruritis NRS, Worst Pruritus Numerical Rating Scale; BSA, body surface area; SC, subcutaneous

## RESULTS

- Cumulatively across 16 weeks in the Measure Up 1 and 2 studies, patients taking UPA 15 mg or UPA 30 mg spent a greater proportion of time with clear skin (EASI 100) or major clinical response (EASI 90-<100) vs placebo. (**Figure 3**)

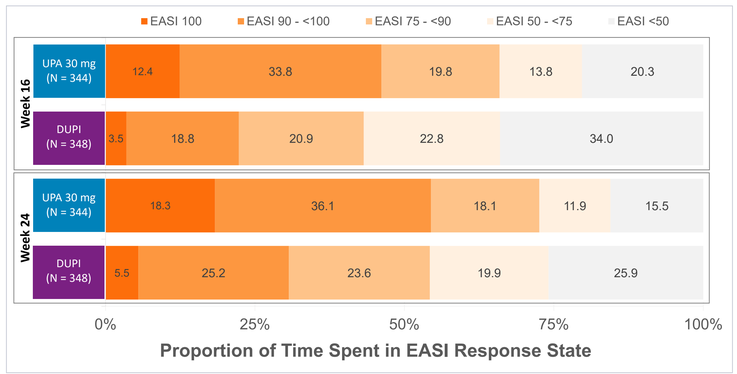
### Figure 3. Measure Up 1 & 2: EASI Response over 16 Weeks




UPA, upadacitinib; DUPI, dupilumab; EASI, Eczema Area and Severity Index

- Cumulatively across 16 and 24 weeks patients taking UPA 30 mg spent a greater proportion of time with clear skin (EASI 100) or major clinical response (EASI 90-<100) vs DUPI. (**Figure 4**)

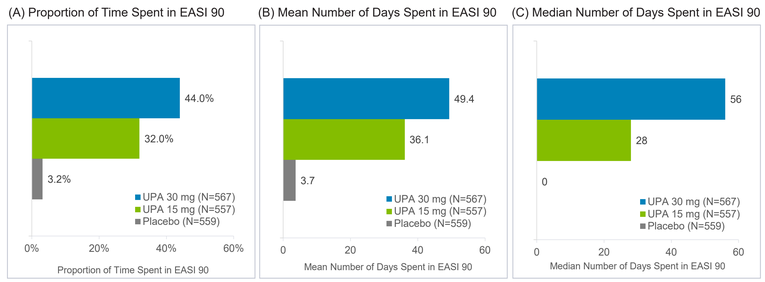
### Figure 4. Heads Up: EASI Response over 16 and 24 Weeks




UPA, upadacitinib; DUPI, dupilumab; EASI, Eczema Area and Severity Index

- Cumulatively across 16 weeks in the Measure Up 1 and 2 studies, patients taking UPA 15 mg or UPA 30 mg spent a greater proportion of time, greater mean number of days, and greater median number of days at EASI 90 compared to placebo. (**Figure 5 A-C**)

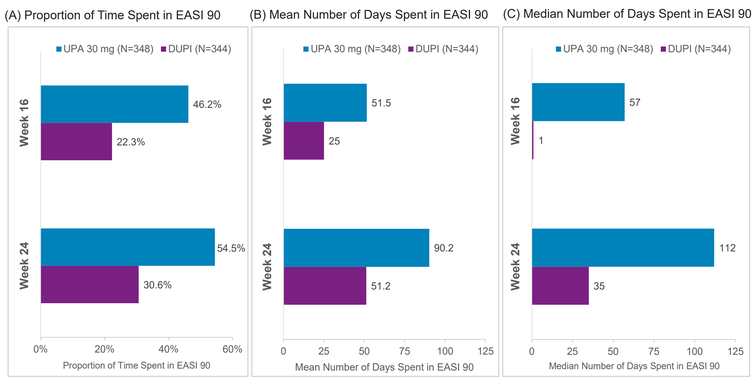
### Figure 5 A-C. Measure Up 1 & 2: Time Spent in EASI 90 over 16 Weeks




UPA, upadacitinib; DUPI, dupilumab; EASI, Eczema Area and Severity Index

- Cumulatively across 16 and 24 weeks patients taking UPA 30 mg spent a greater proportion of time, greater mean number of days, and greater median number of days at EASI 90 compared to DUPI. (**Figure 6 A-C**)

### Figure 6 A-C. Heads Up: Time Spent in EASI 90 at Week 16 and Week 24

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