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The Effect of Upadacitinib on the Genital Region in Moderate-to-Severe Atopic Dermatitis: An Analysis from the Measure Up 1 and Measure Up 2 Studies

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OBJECTIVE

To evaluate the proportion of patients whose genital atopic dermatitis resolved following treatment with upadacitinib 15 mg or upadacitinib 30 mg compared with placebo.

CONCLUSIONS

More patients with moderate-to-severe atopic dermatitis (AD) achieved resolution of genital AD at 2 and 16 weeks with upadacitinib 15 mg or 30 mg monotherapy compared to placebo.

Resolution of genital AD may correspond to improvements in sexual functioning, sleeplessness, and quality of life.

Findings of this study underscore the importance of considering genital involvement when assessing the burden of AD to comprehensively inform shared decision-making treatment discussions between patients and physicians.

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Brian Calimlim, Michael Lane, Stephanie Hays, and Amy Gamelli are full-time employees of AbbVie Inc and may hold AbbVie stock and/or stock options.

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References

1. Guttman-Yassky et al. Lancet. 2021;397(10290):2151-2168.

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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, impacting all body areas, including the genital region.
- Upadacitinib (UPA) is a selective oral Janus kinase (JAK) inhibitor with greater inhibitory potency for JAK1 vs JAK2, JAK3, and tyrosine kinase 2, indicated for the treatment of moderate-to-severe AD.
- Results from phase 3 trials (Measure Up 1, NCT03569293; Measure Up 2, NCT03607422) indicated that UPA 15 mg and UPA 30 mg were superior to placebo in achieving Eczema Area and Severity Index (EASI) improvement of ≥75% from baseline at week 16.[1]
- This post-hoc analysis of the Measure Up 1 and Measure UP 2 studies evaluated the proportion of patients with moderate-to-severe AD whose genital AD resolved with UPA 15 mg or UPA 30 mg compared to placebo.
- This analysis included the SCORing Atopic Dermatitis (SCORAD) measure which assesses the extent and severity to which a body area is affected, as well as itch and sleeplessness due to AD.

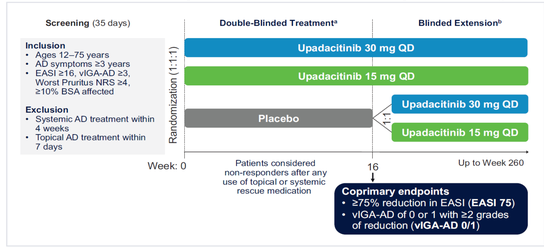
Study Design

- 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**)

Methods

- The current study assessed the proportion of patients with genital involvement at baseline who achieved genital AD resolution at week 2 and week 16.
- Achievement of genital AD resolution was defined as a score of zero on the SCORAD body area assessment for the genital region.
- The proportion of subjects achieving resolution of genital AD at weeks 2 and 16 was determined by comparing each upadacitinib dose versus placebo based on a Mantel-Haenszel test of common risk difference equal to 0 adjusting for study and baseline vIGA-AD.
- P-values for continuous variables are from an ANOVA model; for categorical variables a Cochran-Mantel-Haenszel test of general association was used
- Missing data at study visits were imputed using non-responder imputation (NRI).

Figure 1. Measure Up 1 and Measure Up 2 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

- Of the 1,679 participants in the Measure Up 1 and Measure Up 2 studies, 239 (14.2%) had genital AD at baseline and were randomized to UPA 15 mg (n=77), UPA 30 mg (n=86), or placebo (n=76).
- More participants with genital involvement vs those without were male, ≥18 years old, and severe according to the Validated Investigator Global Assessment Scale for Atopic Dermatitis (vIGA-AD) at baseline. (**Table 1**)
- On average, participants with genital involvement at baseline reported greater disease burden at baseline across multiple domains, including disease duration and Dermatology Life Quality Index (DLQI) scores. (**Table 1**)
- At week 2 and 16 the proportion of patients whose genital AD was resolved was greater in the UPA 15 mg and UPA 30 mg groups compared to placebo.(**Figure 2**)

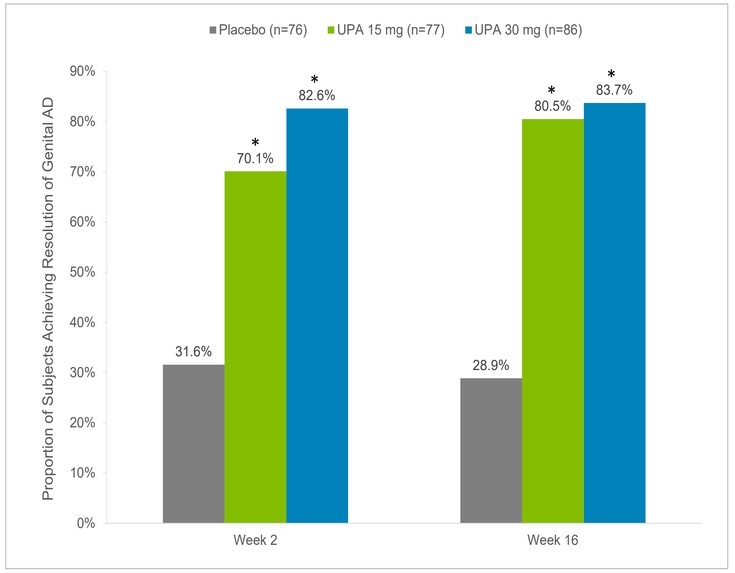
Table 1. Demographics and Baseline Characteristics

	Genital Involvement (n=239)[a]	No Genital Involvement (n=1440)[a]	*p*-value
Demographics			
Sex (male), % (n)	61.1 (146)	54.1 (779)	0.047
Race (White), % (n)	67.8 (162)	67.1 (966)	0.061
Age Group (≥18), % (n)	92.1 (220)	85.5 (1231)	0.007
Clinical Characteristics			
Baseline EASI, mean (SD)	34.3 (13.4)	28.5 (11.7)	<0.001
vIGA-AD - Severe, % (n)	66.9 (160)	47.2 (679)	<0.001
Overall SCORAD, mean (SD)	72.6 (13.3)	66.2 (12.3)	<0.001
Mean Duration of Symptoms (years)	25.0	22.8	0.020
Patient-Reported Measures			
WP-NRS, mean (SD)	7.5 (1.5)	7.2 (1.6)	0.004
POEM, mean (SD)	22.7 (4.6)	21.3 (5.1)	<0.001
DLQI, mean (SD)	19.2 (6.8)	16.3 (6.9)	<0.001
ADerm-SS Skin Pain, mean (SD)	6.8 (2.1)	6.3 (2.2)	0.003
ADerm-IS Sleep, mean (SD)	20.0 (7.1)	18.3 (7.6)	0.001
ADerm-IS Daily Activities, mean (SD)	24.5 (10.4)	22.8 (10.6)	0.032
ADerm-IS Emotional State, mean (SD)	20.4 (8.1)	20.2 (8.1)	0.744
HADS: Anxiety, mean (SD)	7.7 (4.4)	7.3 (4.2)	0.173
HADS: Depression, mean (SD)	6.0 (4.5)	5.3 (4.0)	0.015

[a] Genital involvement is defined as SCORAD genital area affected >0%.

EASI, Eczema Area and Severity Index; vIGA-AD, Validated Investigator Global Assessment Scale for Atopic Dermatitis; WP-NRS, Worst Pruritus Numerical Rating Scale; ADerm-SS, Atopic Dermatitis Symptom Scale; ADerm-IS, Atopic Dermatitis Impact Scale; POEM, Patient-Oriented Eczema Measure; DLQI, Dermatology Life Quality Index; HADS, Hospital Anxiety and Depression Scale; SCORAD, SCORing Atopic Dermatitis

Figure 2. Proportion of Subjects Achieving Resolution of Genital AD at weeks 2 and 16



*p<0.001 vs Placebo; UPA, upadacitinib

Data evaluated among patients with genital AD involvement at baseline. Achievement of genital AD resolution was defined as a score of zero on the SCORAD body area assessment for the genital region.