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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Introduction/Background: Atopic dermatitis (AD) is a chronic, inflammatory skin disease that can be debilitating, impacting all body areas, including the genital region. Genital AD results in impairments in daily activity levels, sexual function, and sleep, contributing to impaired quality of life in patients with moderate-to-severe AD. 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. The SCORing Atopic Dermatitis (SCORAD) measure assesses the extent and severity to which a body area is affected, as well as itch and sleeplessness due to AD.

Objectives: In this post-hoc analysis of the Measure Up 1 and Measure Up 2 studies, we evaluated the proportion of patients whose genital AD resolved with UPA 15 mg or UPA 30 mg compared with placebo.

Methods: Measure Up 1 and 2 are phase 3 multicenter, randomized, double-blind studies comparing the safety and efficacy of UPA 15 mg and UPA 30 mg to placebo in adolescent and adult patients with moderate-to-severe AD. Patients were randomized to oral once daily UPA 15 mg, UPA 30 mg, or placebo. The current study assessed the proportion of patients with genital involvement at baseline who achieved genital AD resolution at week 2 and week 16 based on data collected from the SCORAD. Non-responder imputation was used.

Results: Of the 1,679 participants, 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 (61.1% vs. 54.1%), ≥18 years old (92.1% vs. 85.5%), and severe according to the Validated Investigator Global Assessment Scale for Atopic Dermatitis (66.9% vs. 47.2%) at baseline. On average, participants with genital involvement at baseline also reported greater disease duration (25.0 vs. 22.8 years) and higher Dermatology Life Quality Index (DLQI) scores (19.2 vs. 16.3). At week 2, the proportion of patients whose genital AD was resolved was 70.1% of the UPA 15 mg group, and 82.6% of the UPA 30 mg group, both of which were greater than the placebo group (31.6%; $p<0.001$). At week 16, the proportion of patients whose genital AD was resolved increased in the UPA 15 mg (80.5%) and UPA 30 mg (83.7%) groups, but not in the placebo group (28.9%) which remained lower than both groups ($p<0.001$).

Conclusions: More patients with moderate-to-severe AD achieved resolution of their genital AD with UPA 15 mg or 30 mg monotherapy daily compared to placebo, with >70% rapidly achieving genital AD resolution after 2 weeks and >80% after 16 weeks of UPA treatment. In addition to overall improvements in moderate-to-severe AD with UPA, resolution of genital AD may correspond to improvements in sexual functioning, reductions in sleeplessness, and greater quality of life. These findings underscore the importance of considering genital involvement when assessing the burden of AD to comprehensively inform integrated shared decision-making treatment discussions between patients and physicians.

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