Efficacy and safety of 1.5% ruxolitinib cream in patients with facial and/or neck atopic dermatitis: a randomized, double-blind, decentralized phase 2 study

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Introduction/Background: Atopic dermatitis (AD) is a chronic, relapsing, remitting, pruritic inflammatory skin disease that often manifests in sensitive regions, including the facial/neck region. Although topical therapies are the mainstay of treatment, AD localized to the facial/neck region can be challenging to treat. Thus, there is a need for effective topical therapies for the treatment of facial/neck AD.

Objectives: Here we describe results from a randomized, double-blind, vehicle-controlled decentralized phase 2 study evaluating the efficacy and safety of 1.5% ruxolitinib cream in adolescent and adult patients with facial and/or neck AD (NCT05127421).

Methods: Eligible patients aged 12–70 years with AD for ≥6 months, an Investigator’s Global Assessment (IGA) score of 2 or 3 (overall and in the facial/neck region excluding the scalp), and ≤20% affected total body surface area (BSA; with ≥0.5% on the facial/neck region) were randomized 2:1 to apply twice-daily 1.5% ruxolitinib cream or vehicle continuously for 4 weeks
(vehicle-controlled [VC] period). After Week 4, patients (regardless of initial randomization group) with no safety concerns applied ruxolitinib cream (open label) as needed for 4 weeks. Efficacy was assessed by a dermatologist/central reader using digital photographs captured by a mobile healthcare provider. The primary endpoint was the proportion of patients who achieved ≥75% improvement in Eczema Area and Severity Index (EASI-75) in the head/neck region at Week 4. Secondary endpoints included the proportion of patients who achieved overall EASI-75 and safety (frequency and severity of treatment-emergent adverse events [TEAEs]). Exploratory endpoints included the proportion of patients who achieved an IGA score of 0/1 or IGA treatment success (IGA-TS; IGA score of 0/1 with ≥2-point improvement from baseline) in the facial/neck region and overall. Patients with missing values were imputed as nonresponders for the primary endpoint.

**Results:** Overall, 77 patients were randomized (1.5% ruxolitinib cream, n=54; vehicle, n=23); 66 patients (85.7%) completed the VC period. The median age was 38.0 years (range, 17–66 y), 80.5% of patients were female, and 44.2% were Black. At baseline, mean (SD) overall and head/neck EASI scores were 4.0 (2.5) and 1.2 (0.7), respectively. Mean (SD) overall and head/neck BSA were 5.4% (4.0%) and 2.1% (1.3%), and 67.5% and 64.9% of patients had overall and facial/neck IGA scores of 3, respectively. A greater proportion of patients randomized to ruxolitinib cream vs vehicle achieved head/neck EASI-75 at Week 4 (37.0% [20/54] vs 17.4% [4/23], respectively); however, this difference was not statistically significant (P=0.091). The proportion of patients who achieved overall EASI-75 was similar between treatment groups at Week 4 (ruxolitinib cream, 29.2% [14/48]; vehicle, 33.3% [6/18]). At Week 4, more patients who applied ruxolitinib cream vs vehicle achieved facial/neck IGA-TS (41.7% [20/48] vs 11.1% [2/18], respectively) and overall IGA-TS (29.2% [14/48] vs 11.1% [2/18]) as
well as a facial/neck IGA score of 0/1 (58.3% [28/48] vs 16.7% [3/18]). EASI-75 and IGA-TS improvements (overall and facial/neck) continued through Week 8 among patients who applied ruxolitinib cream from Day 1. During the VC period, TEAEs were reported in 6 patients (11.1%) who applied ruxolitinib cream vs 5 patients (21.7%) who applied vehicle. Application-site reactions were infrequent during the VC period (ruxolitinib cream, 1.9% [n=1]; vehicle, 8.7% [n=2]), and none were reported during the open-label period. No serious TEAEs or discontinuations due to TEAEs were reported among patients who applied ruxolitinib cream.

**Conclusions:** In this phase 2 decentralized study evaluating twice-daily ruxolitinib cream for the treatment of facial and/or neck AD, more patients who applied ruxolitinib cream vs vehicle achieved head/neck EASI-75 and facial/neck IGA-TS. Ruxolitinib cream was well tolerated with no serious TEAEs.

**Keywords:** ruxolitinib cream; facial and/or neck atopic dermatitis (AD); mild to moderate atopic dermatitis (AD); decentralized clinical trial

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