Background

Atopic dermatitis (AD) is a chronic, intensely pruritic, inflammatory skin dermatosis that greatly impacts patients’ quality of life. Ruxolitinib cream is a topical selective inhibitor of JAK1 and JAK2 developed for the treatment of AD in Phase 2 study (NCT01901815), ruxolitinib cream provided high rates of strength dependent efficacy in patients with AD and a safety profile similar to vehicle.

Objective

To evaluate the efficacy and safety of ruxolitinib cream using pooled data from two phase 3 studies (TU2-AD and TU3-AD) and their safety and tolerability in adolescent and adult patients with AD.

Methods

Study Design and Patients

Eligible patients were aged 12 years with AD for ≥12 weeks, on a stable dose of topical corticosteroid therapy for ≥2 weeks. Patients were randomized to vehicle, 0.75% or 1.5% ruxolitinib cream BID, for 12 weeks. Key exclusion criteria were unstable course of AD, other types of scarring, immunocompromised state, use of systemic therapies during the washout period and during the study, use of AD topical therapies except bland emollients, and any serious illness or medical condition that could interfere with study conduct, interpretation of data, or patients well-being.

Study Results

The safety population was randomized to vehicle (n=250), 0.75% (n=483), or 1.5% (n=500) ruxolitinib cream BID. The primary and main secondary endpoints were analyzed by logistic regression. At Week 8, significantly more patients achieved IGA-TS with 0.75% and 1.5% ruxolitinib cream vs vehicle (41.5% vs 15.8%, p<0.0001 for both comparisons; Figure 6) and NRS4 (31.0% vs 12.0%, p<0.0001; Figure 5). Significantly more patients achieved ≥75% improvement in EASI-75 and SCORAD index with 0.75% and 1.5% ruxolitinib cream vs vehicle (36.3% vs 5.5%, p<0.0001; and 28.3% vs 3.0%, p<0.0001, respectively; Figure 3). The largest change from baseline was observed with 0.75% ruxolitinib cream for PRMS and sleep disturbance (PRMS sleep disturbance, 6-point improvement from baseline; n=105, p=0.001; Figure 4). The most common TEAEs were infection (4.4%) and application site reaction (2.1%).

Conclusions

Application of ruxolitinib cream brought about rapid (within 12 hours of initiation of therapy), substantial, and sustained reduction in itch. Ruxolitinib cream demonstrated superior efficacy vs vehicle for achieving IGA-TS, EASI-75, NRS4, and a 26-point improvement in PRMS b, and change from baseline in SCORAD. Ruxolitinib cream demonstrated a dual mode of action: antipruritic and anti-inflammatory. The AE profile was similar to vehicle; the rate of application site reactions was low. These results demonstrate the potential of ruxolitinib cream as an effective and well-tolerated topical treatment for AD.

Disclosures

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References