INTRODUCTION

Types of plaque psoriasis include erythematosus, scaly, well-demarcated plaques frequently associated with pain, itching, or burning that can have a negative effect on quality of life (QoL).

Roflumilast cream (ARQ-151), a potent phosphodiesterase-4 (PDE-4) inhibitor, was under investigation as a once-daily topical treatment for patients with chronic plaque psoriasis in a 12-week, randomized, double-blind, vehicle-controlled phase 2b study (ClinicalTrials.gov ID NCT03830825).

OBJECTIVE

To assess the effect of roflumilast cream on patient-reported signs and symptoms of psoriasis on QoL.

METHODS

Study Design

Design: parallel group, randomized, double-blind, vehicle-controlled phase 2b study at ClinicalTrials.gov, NCT03830825.

Location: 20 sites in the United States and Canada.

Participants: adult patients (≥18 years) with chronic plaque psoriasis.

Eligibility:

- Disease at least mild severity (score ≥2 on 5-point ISA, assessing plaque thickness, scaling, and erythema; a score of 0 indicates “clear” or “minimal disease”)
- Score ≥2 on the modified Psoriasis Area and Severity Index (ranged 0-120, minimal disease)
- Interventions: roflumilast cream 0.3% or 0.15%, or vehicle; once daily for 12 weeks
- Primary endpoint: ISA status of “clear” or “almost clear” (score 0 or 1) at Week 12 in the intent-to-treat population

RESULTS

Assessments of Sign and Symptom Burden and QoL

Psoriasis Symptom Diary (PSD)

- Total score: severity and impact of psoriasis-related signs and symptoms over the past 24 hours.
- Burden of individual signs and symptoms: stinging (PSD Item 4), skin cracking (PSD Item 12). Patients with any TEAE were uncontrolled in this study and were similar across treatment groups (Table 2).

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REFERENCES