Once-Daily Roflumilast Foam 0.3% Improves Severity and Burden of Itch in Patients With Scalp and Body Psoriasis in a Randomized, Double-blind, Vehicle-Controlled Phase 2b Study

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INTRODUCTION

In patients with psoriasis, about 87%-90% have scalp involvement.1–3 Scalp psoriasis is often associated with itch, the most troublesome symptom of psoriasis4; itching, flaking, and plaque visibility on the scalp can cause social embarrassment and adversely impact quality of life.5 Treatment of scalp psoriasis is difficult because the hair may limit efficacy of creams and ointments and reduce treatment adherence.6

Roflumilast is a selective and potent phosphodiesterase 4 inhibitor being investigated as a once-daily, nonsteroidal, topical treatment for various dermatologic conditions.7 Roflumilast foam is uniquely formulated as an emollient, water-based, moisturizing foam that can be used on the scalp or body.8–10 Roflumilast cream met the primary and secondary endpoints and was well tolerated in a phase 2b, randomized, double-blind, vehicle-controlled trial in adults with psoriasis.11–13 We investigated rофlumilast foam for scalp and body psoriasis in an 8-week, randomized, double-blind, vehicle-controlled 8-week study. (ClinicalTrials.gov identifier: NCT04128207)

METHODS

This was a parallel-group, double-blind, vehicle-controlled clinical trial (Figure 1). Eligible patients were adults and adolescents ≥12 years old with diagnosis of scalp and body psoriasis for at least 6 months. Patients were randomized 2:1 to roflumilast 0.3% or matching vehicle foam. The primary efficacy endpoint was Investigator Global Assessment (IGA) Success, defined as achievement of an IGA score of 0 or {\textless}1 and at least a 2-grade improvement in baseline at Week 8. Tolerance endpoints were analyzed using a Cochran-Mantel-Haenszel test stratified by country, baseline IGA, and baseline body (scalp or non-scalp) psoriasis severity.14–15 Statistical tests were conducted at the 5% significance level using 2-sided tests.