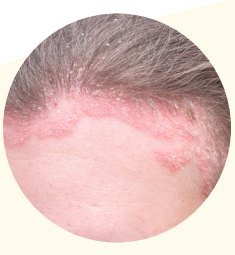
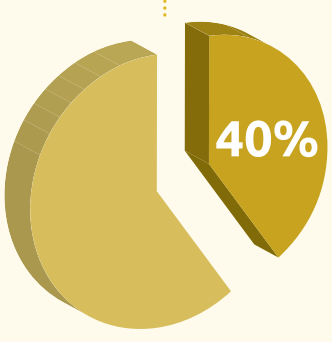
Phase 2 Trial of Roflumilast Foam (ARQ-154) for the **Treatment of Scalp Psoriasis**



WHAT IS SCALP PSORIASIS?

Scalp psoriasis is a manifestation of plaque psoriasis characterized by raised, red areas of skin ("plaques") covered with silvery-white scales, which occurs on the scalp. It may also include the forehead or back of the neck or ears.



have plaques on their scalp

Approximately **40% of the 6 million psoriasis patients** in the U.S. with active disease (or more than 2.5 million patients) have **plaques on their scalp.**

Scalp psoriasis can often be **itchy and painful,** sometimes resulting in **hair loss** due to excessive scratching, rubbing, or combing of the affected area.

SCALP PSORIASIS CAN BE DIFFICULT TO TREAT

Treating the scalp with existing topical formulations like creams, ointments or lotions in hair-bearing areas may be difficult or may make the appearance of hair unacceptable.

Treatments are often combined or alternated due to concerns about side effects or because treatments stop working after repeated use.

Topical roflumilast foam (ARQ-154) is a once-daily, leave-in foam formulation of a highly potent and selective PDE4 inhibitor that is being developed to treat inflammatory dermatoses, especially in hair-bearing areas of the body such as the scalp, and that can be used with no limitation on duration of use.

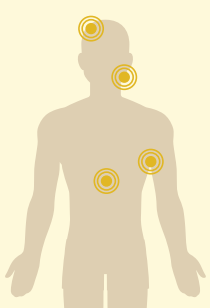
STUDY DESIGN[2]

305 PEOPLE
ADULTS & ADOLESCENTS

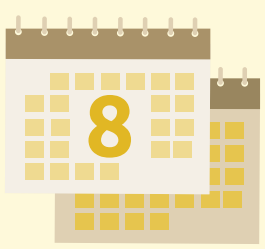
≥12 YEARS
OF AGE

> 6 MONTHS
WITH PLAQUE PSORIASIS

Global, double-blind, vehicle-controlled trial at **47 clinical research locations.**



Patients with a diagnosis of at least **mild plaque psoriasis on the scalp and body.**



Applied once daily for 8 weeks in patients randomly assigned to receive roflumilast foam 0.3% or placebo vehicle.

1 Primary Endpoint

The primary endpoint is **Scalp Investigator Global Assessment Scale** (S-IGA) success, defined as achievement of a rating of clear or almost clear plus a 2-grade improvement at week 8 on the IGA scale of the scalp.*

2 Secondary Endpoints

- Body Investigator Global Assessment (B-IGA) Scale
- Psoriasis Scalp Severity Index (PSSI)
- Scalp Itch Numeric Rating Scale (SI-NRS)
- Psoriasis Symptom Diary (PSD)

For more information, visit www.ClinicalTrials.gov, Identifier: NCT04128007.

**IGA is a 5-point scale assessing disease severity ranging from 0-clear, 1-almost clear to 4-severe.*

TOPLINE STUDY RESULTS

Once-daily roflumilast foam demonstrated statistically significant improvement over the vehicle foam on the trial's primary endpoint and met multiple secondary endpoints in patients with plaque psoriasis that includes plaques on the scalp.

Primary Endpoint

At week 8, roflumilast foam 0.3% achieved a **Scalp Investigator Global Assessment (S-IGA) success**** rate of 59.1% compared to a vehicle rate of 11.4% ($p < 0.0001$).

Secondary Endpoints

At week 8, roflumilast foam 0.3% achieved a **Body IGA (B-IGA) success rate of 40.3%** compared to a vehicle rate of 6.8% ($p < 0.0001$).

Roflumilast foam 0.3% achieved **a SI-NRS 4-pt response in 71.0% of patients** compared to a vehicle rate of 18.5% ($p < 0.0001$) at week 8.***

SAFETY

Key Takeaway

Once-daily roflumilast foam demonstrated a favorable safety and tolerability profile.

Roflumilast foam was **well-tolerated**, with low rates of adverse events, treatment-related adverse events, and discontinuations due to adverse events, and all rates were similar to vehicle.

Only 5 out of 198 subjects (2.5%) treated with roflumilast foam discontinued the study due to an adverse event, compared to 2 out of 104 subjects (1.9%) treated with the vehicle.

*** S-IGA success is defined as the achievement of an S-IGA score of 'clear' or 'almost clear' on a 5-grade scale plus at least a two-point change from baseline.*
**** In patients with a baseline on the SI-NRS of at least 4.*

These positive results highlight the potential of roflumilast once-daily foam as a safe, convenient topical treatment option for chronic use that is appropriate for application on all areas of the body, particularly hair-bearing areas, such as the scalp, where a cream, lotion, or ointment is not suitable.

For full results and information, visit www.arcutis.com

1. Merola et al. Dermatol Ther. 018;31:e12589
2. https://www.clinicaltrials.gov/ct2/show/NCT04128007?term=ARQ-154&draw=2&rank=2. Accessed on October 26, 2020.

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