ARCUTIS BIOTHERAPEUTICS

Phase 2 Trial of Roflumilast Foam (ARQ-154) for the **Treatment of Seborrheic Dermatitis**

ROFLUMILAST FOAM (ARQ-154)

Roflumilast foam (ARQ-154) is an investigational once-daily, non-steroidal, anti-inflammatory topical formulation of a highly potent PDE4 inhibitor designed to be used on all parts of the body, ***especially*** hair-bearing areas, in patients with seborrheic dermatitis.

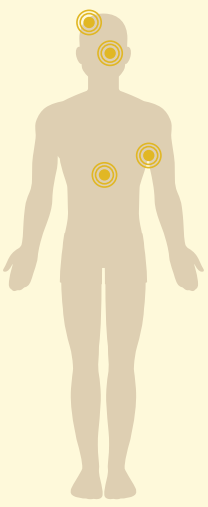
STUDY DESIGN[1]

226 ADULTS
MEN AND WOMEN

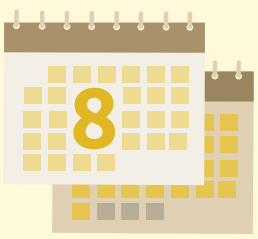
≥18 YEARS
OF AGE

≥3 MONTHS
WITH SEBORRHEIC DERMATITIS

Double-blinded, vehicle-controlled trial at **24 clinical research locations** (U.S. and Canada).



Adults with moderate-to-severe seborrheic dermatitis affecting the **scalp, face, trunk and/or intertriginous areas**.



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

1 Primary Endpoint

The primary endpoint is **achievement of clear or almost clear plus a 2-grade improvement at week 8** on the Investigator Global Assessment Scale (IGA) scale.*

2 Secondary Endpoints

The secondary endpoints include:
- Overall assessment of erythema
- Overall assessment of scaling
- Worst itch numeric rating

For more information, visit www.ClinicalTrials.gov, Identifier: NCT04091646.

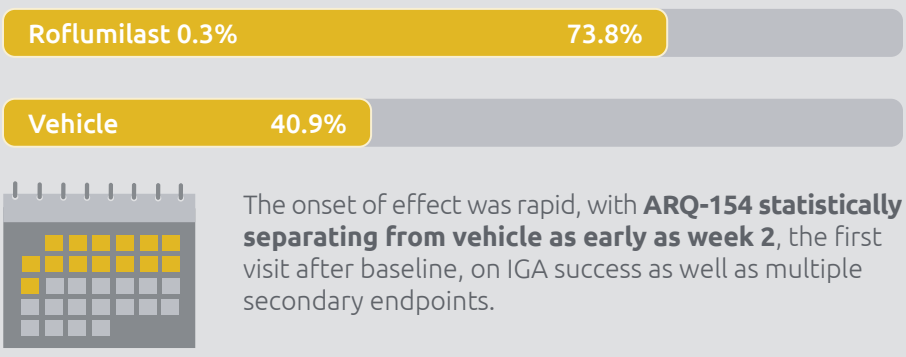
**IGA is a 5-point scale assessing disease severity ranging from 0-clear, 1-almost clear to 4-severe.*

TOPLINE STUDY RESULTS

Roflumilast foam demonstrated statistically significant improvement over the vehicle foam on the trial's primary and multiple secondary endpoints in treated patients with moderate-to-severe seborrheic dermatitis.

Primary Endpoints

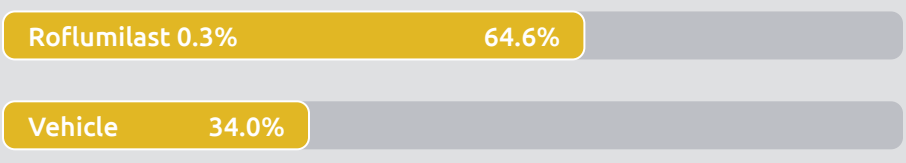
At week 8, roflumilast foam 0.3% achieved an **IGA success** rate of 73.8%** compared to a vehicle rate of 40.9% (p<0.0001).



The onset of effect was rapid, with **ARQ-154 statistically separating from vehicle as early as week 2**, the first visit after baseline, on IGA success as well as multiple secondary endpoints.

Secondary Endpoints

At week 8, 64.6% of subjects treated with roflumilast foam who had a baseline Worst Itch Numeric Rating Scale (WI-NRS) score of **≥ 4 achieved an itch reduction of at least 4 points** compared to 34.0% of vehicle treated subjects (p=0.0007).



***IGA success is defined as the achievement of an IGA score of 'clear' or 'almost clear' on a 5-grade scale PLUS at least a two-point change from baseline.*

SAFETY

Key Takeaway

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

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

Only 2 out of 154 subjects (1.3%) treated with roflumilast foam discontinued the study due to an adverse event, compared to 1 out of 72 subjects (1.4%) treated with the vehicle.

These positive results highlight the potential of once-daily roflumilast foam to revolutionize the standard of care as a "best-in-class" treatment for patients living with seborrheic dermatitis.

www.arcutis.com

1. https://clinicaltrials.gov/ct2/show/NCT04091646?cond=Seborrheic+Dermatitis&draw=2&rank=7 Accessed on Sept. 10, 2020.