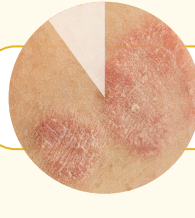


# Phase 2B Trial of Roflumilast Cream (ARQ-151) for the Treatment of Chronic Plaque Psoriasis

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## KEY FACTS

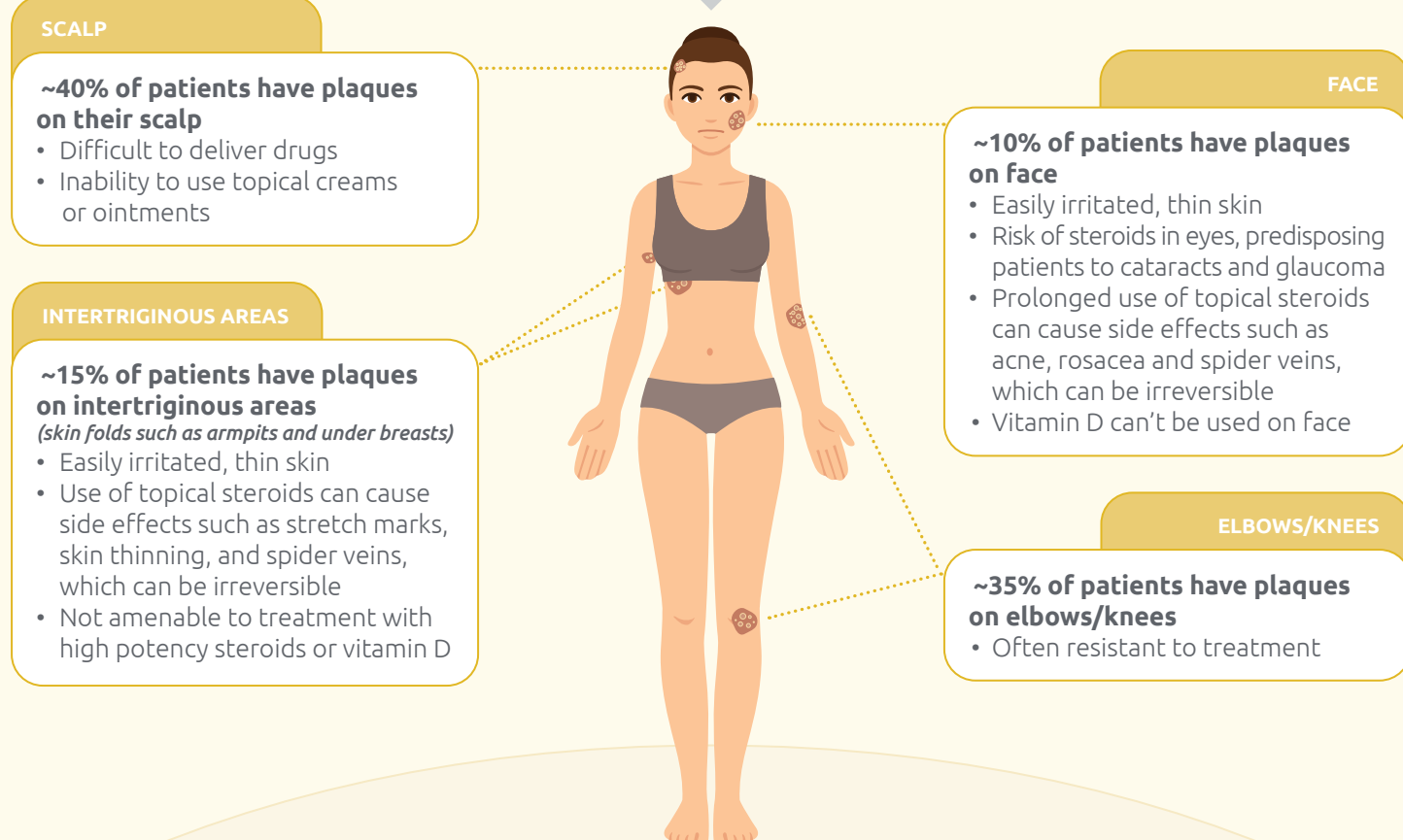
Psoriasis is a chronic, inflammatory skin disorder that affects more than **8 million people** in the U.S.<sup>1</sup>



**90% of cases are plaque psoriasis**, which results in painful itchy raised areas of erythematous (red) skin covered by white or silvery scales and can be associated with poor quality of life.

### Location of disease poses specific treatment challenges

Plaque psoriasis can appear on any area of the body, but often appears on the scalp, knees, elbows, face and intertriginous areas.



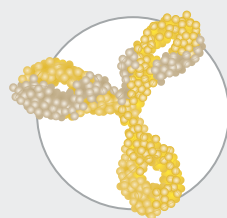
## CURRENT TREATMENT OPTIONS

Current treatments have limitations.



### Topical Treatments

- Used by 90% of psoriasis patients in the U.S.
- High potency topical steroids show improvement — but use limited to 2–8 weeks
- Vitamin D analogues offer less benefit, are often irritating, and are contraindicated on the face and intertriginous areas



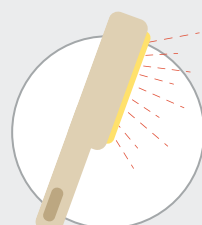
### Biologics

- Injectable treatments that target specific proteins in the body
- Use restricted to moderate-to-severe disease (25% of patient population)
- Not indicated in patients with mild-to-moderate disease (75% of patient population)
- Only used in ~6% of patients with psoriasis
- Very high cost



### Oral Medications

- Limited to use in patients with moderate-to-severe disease
- Side effects are significant and efficacy is less than biologics



### Phototherapy

- Ultraviolet light therapy used alone or combination with medications
- Risk of skin irritation, skin cancers with long-term use
- Inconvenient for patients, requiring frequent, lengthy visits to doctor



**Did you know?** No novel mechanisms of action for topical treatments for psoriasis have been approved by the FDA in **over 20 years**.

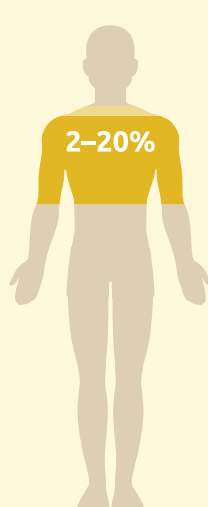
## STUDY DESIGN

**331 ADULTS**

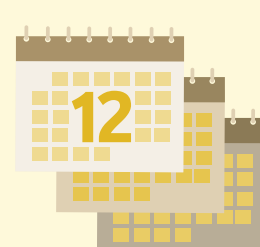
**≥18 YEARS**  
OF AGE

**> 6 MONTHS**  
WITH PLAQUE PSORIASIS

Double-blinded, vehicle-controlled trial at **30 clinical research locations** (U.S. and Canada).



Adults with mild, moderate, or severe chronic plaque psoriasis affecting **2%–20% body surface area (BSA)** excluding the scalp, palms, and soles.



Dosing once daily for **12 weeks** with patients randomly assigned to receive roflumilast cream 0.3%, 0.15%, or vehicle cream.



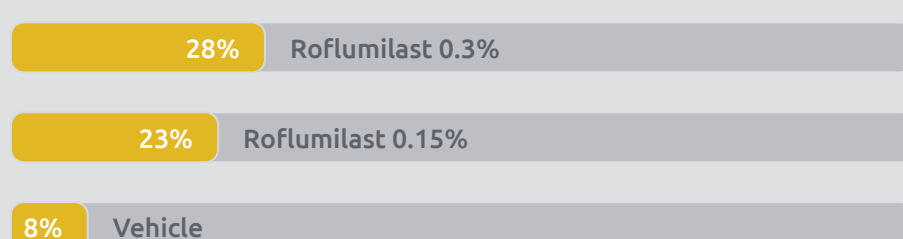
**Roflumilast cream (ARQ-151)** is a highly potent, selective phosphodiesterase-4 (PDE-4) inhibitor in a convenient, once-daily cream being developed for chronic plaque psoriasis. Roflumilast is 25–300X more potent than other PDE-4 inhibitors used in dermatology.

## STUDY RESULTS

Roflumilast demonstrated statistically significant improvement over the vehicle cream on key psoriasis efficacy endpoints.

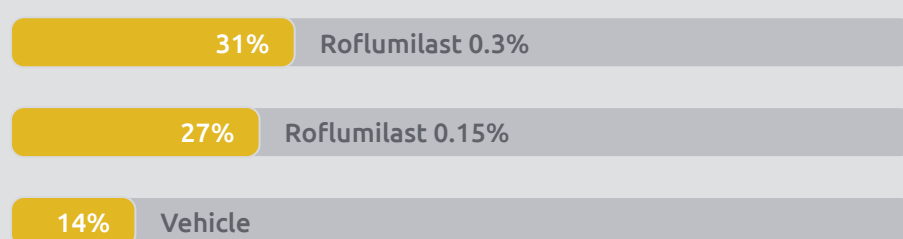
### Primary Endpoint

Patients treated once-daily with roflumilast achieved clear or almost clear state at Week 6 on the Investigator Global Assessment (IGA) scale\*.



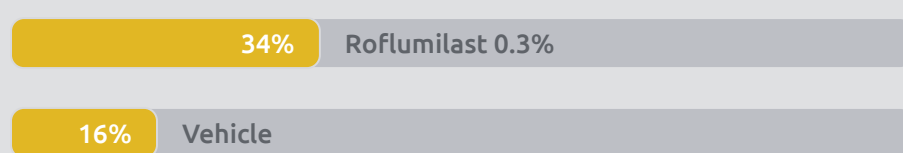
### Secondary Endpoints

From Week 6 through Week 12, patients treated once-daily with roflumilast achieved separation from vehicle in IGA of clear or almost clear plus 2-grade improvement from baseline (IGA success). At Week 12:



Approximately 15% of patients had intertriginous psoriasis of at least mild severity at baseline; **93% of these patients treated with roflumilast 0.3% had an Intertriginous-IGA score of 0 (clear) at Week 12**.

Patients treated once-daily with roflumilast achieved improvements in Psoriasis Area and Severity Index (PASI) of at least 75% at 12 weeks:



Significant improvements in **itch** and **burden of disease** were seen **as early as 2 weeks of treatment**.

\* Investigator Global Assessment (IGA) is a 5-point scale assessing disease severity ranging from 0-clear and 1-almost clear to 4-severe.

## SAFETY

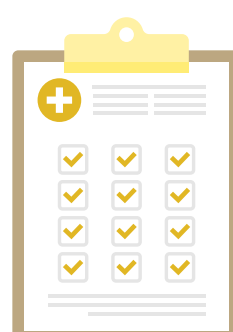
### Key Takeaway

Both doses of roflumilast cream were very well tolerated in the trial.



**97% of AEs were rated mild or moderate in severity.**

Most common were upper respiratory tract infection/viral upper respiratory tract infection and nasopharyngitis.



**94% of patients** treated with roflumilast 0.3% **completed full 12 weeks** of study.

**Rates of application site reactions were low** and were similar between roflumilast and vehicle groups.

**These positive results highlight the potential of roflumilast once-daily cream as a 90%, non-steroidal topical for chronic plaque psoriasis.**

**For full results and information, visit [www.arcutis.com](http://www.arcutis.com)**