FDA Approves Roflumilast Topical Foam 0.3% for Plaque Psoriasis in Adults and Children

Key Takeaways

- Roflumilast topical foam 0.3% is FDA-approved for plaque psoriasis in patients aged 12 and older, effective for body and scalp treatment.
- It is a once-daily, steroid-free PDE4 inhibitor, increasing proinflammatory mediators and decreasing anti-inflammatory mediators.
- Roflumilast is the only branded topical therapy for atopic dermatitis, seborrheic dermatitis, and plaque psoriasis.
- The approval provides a convenient, long-term treatment option without duration limitations, marking the fifth approval for roflumilast in under three years.

This indication is for adult and pediatric patients aged 12 and older with plaque psoriasis of the scalp and body.

The FDA approved the supplemental new drug application (sNDA) for roflumilast (Zoryve; Arcutis Biotherapeutics) topical foam 0.3% for the treatment of adult and pediatric patients aged 12 years and older with plaque psoriasis of the scalp and body. This sNDA was accepted by the FDA in September 2024.1,2 According to a news release, roflumilast foam demonstrated significant improvements in signs and symptoms of psoriasis on both the body and scalp during clinical trials.[1]

Roflumilast topical foam is a once-daily, steroid-free topical that is now widely available as a treatment for patients with plaque psoriasis. It is a next-generation topical phosphodiesterase-4 (PDE4) inhibitor, which is an intracellular enzyme that increases the production of proinflammatory mediators while decreasing the production of anti-inflammatory mediators.1,2 According to the news release, roflumilast is the only branded topical therapy for 3 major inflammatory dermatological conditions: atopic dermatitis (eczema), seborrheic dermatitis, and plaque psoriasis.[1]

“Treating plaque psoriasis in areas like the scalp, face, and groin is especially challenging. A safe, effective foam offers a much-needed solution,” clinical trial investigator Jennifer Soung, MD, director of clinical research at Southern California Dermatology, said in a news release. “In clinical trials, [roflumilast] foam not only effectively cleared psoriasis plaques on the body and scalp, but also provided rapid itch relief. [Roflumilast] can be safely used for any duration and offers 2 highly convenient formulations, cream or foam, for health care providers to choose from. [Roflumilast] foam allows patients to treat their whole body with 1 prescription, transforming the treatment landscape for scalp and body psoriasis.”[1]

The approval is supported by positive results from the phase 2 Trial 204 (NCT04128007) and phase 3 ARRECTOR (NCT05028582)3, both of which were multicenter, randomized, double-blind, vehicle-controlled studies evaluating the safety and efficacy of roflumilast foam 0.3% in

patients with plaque psoriasis. Cumulatively, the trials enrolled 736 adolescents and adults aged 12 years and older with mild to severe plaque psoriasis of the scalp and body. In both trials, patients were randomly assigned to receive roflumilast or a vehicle foam, both of which are applied once daily for an 8-week duration.[1,3,4]

The ARRECTOR study was observed to meet its co-primary end points of Scalp-Investigator Global Assessment (S-IGA) Success and Body-Investigator Global Assessment (B-IGA) Success. For S-IGA, approximately 66.4% of patients treated with roflumilast compared with 27.8% of individuals treated with a matching vehicle foam achieved S-IGA Success at the 8-week point ($P < .0001$). For B-IGA, more patients receiving roflumilast had achieved B-IGA Success at week 8 (45.5% vs 20.1%; $P < .0001$).[1,4]

Further, Trial 204 met its primary end point with about 56.7% of individuals treated with roflumilast foam achieving S-IGA Success at week 8 compared with 11.0% of those receiving vehicle foam ($P < .0001$). Additionally, 39.0% and 7.4% of patients in these respective groups achieved B-IGA Success ($P < .0001$).[1]

Roflumilast foam had also provided a clinically meaningful improvement in itch. In ARRECTOR, 65.3% of patients achieved a clinically significant reduction in scalp itch compared with approximately 30.3% of those treated with vehicle ($P< .0001$; measured by a $\geq$ 4-point change from baseline in Scalp Itch-Numeric Rating Scale [SI-NRS]). A greater improvement in scalp itch was observed 24 hours following the first application of roflumilast foam. The improvement in scalp itch was consistent in Trial 204, with a higher percentage of individuals achieving SI-NRS Success at the 8-week period with roflumilast compared to vehicle (67.3% vs. 20.7%, respectively).[1,4]

There was also an improvement in body itch as measured by the Worst Itch-Numeric Rating Scale (WI-NRS), with 63.1% of those treated with roflumilast achieving a at least a 4-point reduction in WI-NRS compared with 30.1% of those treated with vehicle ($P < .0001$).[1,4]

Overall, the PDE4 inhibitor was well-tolerated by participants. The incidence of treatment-emergent adverse events (TEAEs) was low and generally similar between active treatment and vehicle, with most TEAEs considered to be mild to moderate in severity. The most common AEs for roflumilast combined (≥1%) included headache (3.1%), diarrhea (2.5%), nausea (1.7%), and nasopharyngitis (1.3%). Further, rates of discontinuation because of AEs were low and similar among roflumilast-treated and vehicle-treated patients in the pooled study populations.[1,4]

“Individuals living with psoriasis, a chronic inflammatory skin disease, want treatments that are not only safe and effective for long-term use but also convenient. With approval for cream and now the foam formulations, individuals and clinicians can choose their preferred administration of [roflumilast] with powerful, long-term relief of plaques and itch anywhere on the body, including hair-bearing areas, with no limitation on duration of use,” Frank Watanabe, president and CEO of Arcutis Biotherapeutics, said in the news release. “This is the fifth approval for

[roflumilast] in less than 3 years and furthers our mission to deliver new treatment options that address the urgent needs of individuals suffering from chronic inflammatory skin diseases."[1]

REFERENCES

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2. GlobeNewswire. FDA Accepts Arcutis' Supplemental New Drug Application for ZORYVE® (roflumilast) Foam for the Treatment of Scalp and Body Psoriasis in Adults and Adolescents Ages 12 and Over. September 24, 2024. Accessed May 22, 2025. https://www.globenewswire.com/en/news-release/2024/09/24/2952078/0/en/FDA-Accepts-Arcutis-Supplemental-New-Drug-Application-for-ZORYVE-roflumilast-Foam-for-the-Treatment-of-Scalp-and-Body-Psoriasis-in-Adults-and-Adolescents-Ages-12-and-Over.html

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