Arcutis Announces Publication of Positive Long-Term Safety and Efficacy Data of ZORYVE® (roflumilast) Foam 0.3% in Individuals with Seborrheic Dermatitis in American Journal of Clinical Dermatology

November 4, 2025

- ZORYVE foam 0.3% was safe, well-tolerated, and demonstrated durable and continuously improving efficacy in the treatment of seborrheic dermatitis up to 52 weeks
- Once-daily ZORYVE foam 0.3% is approved to treat seborrheic dermatitis in adults and adolescents 9 years of age and older

WESTLAKE VILLAGE, Calif., Nov. 04, 2025 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on immuno-dermatology, today announced that the *American Journal of Clinical Dermatology* published data from the Phase 2 long-term safety open-label extension (OLE) study that demonstrated once-daily ZORYVE® (roflumilast) foam 0.3% is safe, well-tolerated, and efficacious for up to 52 weeks of treatment in individuals with seborrheic dermatitis. ZORYVE foam was approved in December 2023 by the U.S. Food & Drug Administration (FDA) for the topical treatment of seborrheic dermatitis in adults and adolescents 9 years of age and older; in 2025 it was also approved for the topical treatment of scalp and body plaque psoriasis in adults and adolescents 12 years of age and older and is available in pharmacies nationwide.

“In my practice, I often see individuals with seborrheic dermatitis struggling with persistent itching, redness, and scaling in visible areas like the scalp, face, and chest. For many, this chronic condition is not only uncomfortable but also affects their self-esteem and quality of life,” said Andrew Alexis, MD, MPH, New York-based dermatologist and lead author of the paper. “While topical antifungals, topical corticosteroids, and medicated shampoos are often used, these treatment routines can be complex and often fall short of desired patient outcomes. ZORYVE foam represents a meaningful advancement for individuals living with this burdensome disease.”

This Phase 2, open-label safety trial was conducted in individuals aged ≥12 years with moderate to severe seborrheic dermatitis who had previously been treated with ZORYVE foam in a separate Phase 2 double-blind study or were treatment-naive. During the study, all participants (n=400) applied ZORYVE foam once daily, as a monotherapy treatment, to all areas of their bodies impacted by seborrheic dermatitis, including on the scalp, face, trunk, and intertriginous areas. Once patients' disease had cleared (IGA=0) they were able to stop treatment and restart with any sign of disease returning. Of the 400 participants, 338 participants were enrolled for 24 weeks and 62 participants were enrolled to continue through 52 weeks.

The primary endpoint was safety. Treatment-Emergent Adverse Events (TEAEs) were reported for 130 (32.5%) participants. The most common TEAE (≥2%) was COVID-19, which was reported for 15 (3.8%) participants, followed by headache in 13 (3.3%) participants. Serious Adverse Events (SAEs) were reported for 7 (1.8%) individuals, none of which were considered treatment related. Overall, 5 of 400 participants (1.3%) discontinued the trial because of an AE.

Based on investigator-rated local tolerability assessments, ≥96% of study participants had no evidence of local irritation. For patient-reported local tolerability assessments, ≤1.1% of participants reported a stinging sensation at the application site. Additionally, most participants with hyperpigmentation or hypopigmentation at baseline experienced full resolution by the end of the study.

As previously reported, durable and continuously improving efficacy was observed in the study. In individuals who completed 52 weeks of treatment with ZORYVE foam (n=46), 24 (52.2%) achieved an Investigator Global Assessment (IGA) of Clear (0) at Week 52. On the assessment of IGA of Clear or Almost Clear (0 or 1), 56.4% (219/388) attained this level of efficacy at Week 4, 76% (260/342) at Week 24, and 80.4% (37/46) at Week 52. Moreover, ZORYVE foam treatment resulted in high proportions of participants with no erythema (redness) and scaling throughout the trial.

Treatment with ZORYVE foam resulted in sustained improvement in itch, as measured by the Worst Itch Numeric Rating Scale (WI-NRS), with 71.3% (189/265) of participants with WI-NRS ≥4 at baseline achieving a clinically significant response (≥4-point improvement) at Week 24 and 58.1% at Week 52 (18/31).

“Seborrheic dermatitis is a common, chronic inflammatory skin disease and data on its pathophysiology published over the last year demonstrate it has a distinct immunological and molecular profile, including a unique skin barrier disruption. ZORYVE foam is the first topical with a new mechanism of action approved for seborrheic dermatitis in 20 years,” said Patrick Burnett, MD, PhD, FAAD, chief medical officer, Arcutis Biotherapeutics. “The publication of these data reinforces the strong efficacy and safety of once-daily ZORYVE foam and underscores our dedication to providing dermatologists and individuals living with chronic inflammatory skin conditions with treatment options that can be used with confidence over the long term.”

About ZORYVE® (roflumilast)
ZORYVE is the number one prescribed branded topical therapy across three major inflammatory dermatoses combined—atopic dermatitis, seborrheic dermatitis, and plaque psoriasis. ZORYVE is a topical formulation of roflumilast, an advanced targeted topical phosphodiesterase type 4 (PDE4) inhibitor. Inhibiting PDE4, an intracellular enzyme that is an established target in dermatology, decreases the production of pro-inflammatory mediators. This decreases inflammation in the skin and balances the skin’s immune system.

ZORYVE was awarded by *Allure* with a prestigious "2025 Best of Beauty Breakthrough Award," making it the first FDA-approved medication for atopic dermatitis, plaque psoriasis, and seborrheic dermatitis to win this prominent award. ZORYVE cream 0.3% is approved by the FDA for the topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older. ZORYVE cream 0.15% is approved by the FDA for the topical treatment of mild to moderate atopic dermatitis in patients 6 years of age and older. In 2024, ZORYVE cream 0.15% was

awarded *Glamour's* Beauty and Wellness Award for "Eczema Product." Additionally, the American Academy of Dermatology (AAD) issued a strong recommendation for the use of ZORYVE cream 0.15% in adult patients with mild to moderate atopic dermatitis, according to updated guidelines released June 26, 2025. ZORYVE topical foam 0.3% is approved by the FDA for the topical treatment of plaque psoriasis of the scalp and body in patients 12 years of age and older, as well as seborrheic dermatitis in patients 9 years of age and older. Both ZORYVE cream 0.3% and ZORYVE foam 0.3% were awarded the National Psoriasis Foundation's Seal of Recognition—the first FDA-approved product to receive the honor.

INDICATIONS
ZORYVE cream, 0.05%, is indicated for topical treatment of mild to moderate atopic dermatitis in pediatric patients 2 to 5 years of age.

ZORYVE cream, 0.15%, is indicated for topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older.

ZORYVE cream, 0.3%, is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in adult and pediatric patients 6 years of age and older.

ZORYVE topical foam, 0.3%, is indicated for the treatment of plaque psoriasis of the scalp and body in adult and pediatric patients 12 years of age and older.

ZORYVE topical foam, 0.3%, is indicated for the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older.

IMPORTANT SAFETY INFORMATION
ZORYVE is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C).

Flammability: The propellants in ZORYVE foam are flammable. Avoid fire, flame, and smoking during and immediately following application.

The most common adverse reactions reported (≥1%) for ZORYVE cream 0.05% for pediatric patients with atopic dermatitis 2 to 5 years of age were upper respiratory tract infection (4.1%), diarrhea (2.5%), vomiting (2.1%), rhinitis (1.6%), conjunctivitis (1.4%), and headache (1.1%).

The most common adverse reactions reported (≥1%) for ZORYVE cream 0.15% for patients with atopic dermatitis 6 years of age or older were headache (2.9%), nausea (1.9%), application site pain (1.5%), diarrhea (1.5%), and vomiting (1.5%).

The most common adverse reactions reported (≥1%) for ZORYVE cream 0.3% for plaque psoriasis were diarrhea (3.1%), headache (2.4%), insomnia (1.4%), nausea (1.2%), application site pain (1.0%), upper respiratory tract infection (1.0%), and urinary tract infection (1.0%).

The most common adverse reactions reported (≥1%) for ZORYVE foam 0.3% for plaque psoriasis were headache (3.1%), diarrhea (2.5%), nausea (1.7%), and nasopharyngitis (1.3%).

The most common adverse reactions reported (≥1%) for ZORYVE foam 0.3% for seborrheic dermatitis were nasopharyngitis (1.5%), nausea (1.3%), and headache (1.1%).

Please see full Prescribing Information for ZORYVE foam and full Prescribing Information for ZORYVE cream.

About Arcutis
Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a commercial-stage medical dermatology company that champions meaningful innovation to address the urgent needs of individuals living with immune-mediated dermatological diseases and conditions. With a commitment to solving the most persistent patient challenges in dermatology, Arcutis has a growing portfolio of advanced targeted topicals approved to treat three major inflammatory skin diseases. Arcutis' unique dermatology development platform coupled with our dermatology expertise allows us to develop differentiated therapies against biologically validated targets, and has produced a robust pipeline for a range of inflammatory dermatological conditions. For more information, visit www.arcutis.com or follow Arcutis on LinkedIn, Facebook, Instagram, and X.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. For example, statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements are based on the Company's current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding the long-term use of ZORYVE in seborrheic dermatitis patients. These statements are subject to substantial known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. Risks and uncertainties that may cause our actual results to differ include risks inherent in our business, reimbursement and access to our products, the impact of competition and other important factors discussed in the "Risk Factors" section of our Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on February 25, 2025, as well as any subsequent filings with the SEC. Any forward-looking statements that the company makes in this press release are made pursuant to the Private Securities Litigation Reform Act of 1995, as amended, and speak only as of the date of this press release. Except as required by law, we undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

Contacts
Media
Amanda Sheldon, Head of Corporate Communications
media@arcutis.com

Investors
Brian Schoelkopf, Head of Investor Relations
ir@arcutis.com