Arcutis' ZORYVE® (roflumilast) Cream Receives Strong Recommendation in American Academy of Dermatology First-Ever Pediatric Atopic Dermatitis Guidelines

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- Strong recommendation with high certainty of clinical evidence underscores proven efficacy, safety, and tolerability of ZORYVE cream as a steroid-free topical phosphodiesterase type 4 (PDE4) inhibitor
- Atopic dermatitis affects approximately 9.6 million children in the United States

WESTLAKE VILLAGE, Calif., April 22, 2026 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company dedicated to developing meaningful innovations in immuno-dermatology, today announced that ZORYVE® (roflumilast) cream has received a strong recommendation, with high certainty of clinical evidence, in the American Academy of Dermatology (AAD) clinical practice guidelines for the management of pediatric atopic dermatitis.

The AAD's evidence-based guidelines recommend the use of ZORYVE cream 0.05% for children aged 2-5 years and ZORYVE cream 0.15% for children aged 6 years and older with mild to moderate atopic dermatitis, recognizing its efficacy, safety, and tolerability. The recommendation reinforces ZORYVE's ability to deliver clinically meaningful improvements in disease severity and itch with very low rates of treatment discontinuation, offering an effective topical suitable for long-term use anywhere on the body in both children and adolescents. In clinical trials, the most common adverse reactions reported (≥1%) for ZORYVE cream 0.05% for pediatric patients 2 to 5 years of age with atopic dermatitis were upper respiratory tract infection, diarrhea, vomiting, rhinitis, conjunctivitis, and headache. The most common adverse reactions reported (≥1%) for ZORYVE cream 0.15% for patients 6 years of age or older with atopic dermatitis were headache, nausea, application site pain, diarrhea, and vomiting.

"The AAD's strong recommendation for ZORYVE cream, building on its previous strong recommendation in adults, reflects the high certainty of evidence supporting its efficacy, low rates of treatment discontinuation, and favorable tolerability in pediatric patients. These evidence-based recommendations help clinicians make informed treatment decisions for children, adolescents, and their caregivers managing this chronic condition and reinforce the value of ZORYVE as a topical PDE4 inhibitor," said Patrick Burnett, MD, PhD, FAAD, chief medical officer at Arcutis. "Since atopic dermatitis is a lifelong condition that often begins in childhood, when the immune system and skin barrier are still developing, it is critical to have therapies that balance efficacy with long-term safety and tolerability. ZORYVE does not include ingredients or irritants known to compromise the skin barrier, which is especially important in these age groups."

The pediatric guidelines were developed by a multidisciplinary workgroup using a systematic evidence review and the GRADE framework to assess certainty of evidence and strength of recommendations. The update includes 27 evidence-based recommendations spanning topical therapies, phototherapy, and systemic treatments for children and adolescents under 18 years of age. Among topical phosphodiesterase-4 inhibitors, ZORYVE cream received a strong recommendation supported by high-certainty of evidence, based on multiple randomized controlled trials demonstrating significant improvements in clinical signs, pruritus (itch), and patient-reported outcomes with a favorable tolerability profile. Overall, the guidelines emphasize that topical therapies, including both prescription topical treatments and nonprescription moisturizers, are the "cornerstone of atopic dermatitis management as these therapies are generally effective and lower risk than systemic therapies."

For more information on ZORYVE, including full prescribing information, please visit www.zoryve.com.

About Atopic Dermatitis
Atopic dermatitis is the most common type of eczema and occurs with the highest prevalence in children, affecting approximately 9.6 million children and 16.5 million adults in the United States. Atopic dermatitis is a chronic, relapsing, and genetically predisposed inflammatory skin disease that can significantly impact quality of life for both patients and caregivers. The disease presents with intensely itchy, inflamed skin and may appear differently across the pediatric age spectrum, from infancy through adolescence.

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.

Demonstrating both clinical impact and broad industry recognition, ZORYVE has been honored with multiple prestigious awards and recommendations. ZORYVE was awarded by *Allure* with the "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% and ZORYVE foam 0.3% were also awarded the National Psoriasis Foundation's Seal of Recognition — the first FDA-approved prescription brand to receive the honor. 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 in June 2025. In 2024, ZORYVE cream 0.15% was awarded *Glamour's* Beauty and Wellness Award for "Best Eczema Product."

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.

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

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%).

Please see 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 potential of ZORYVE cream to advance the standard of care in atopic dermatitis, including pediatric 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, 2026, 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.

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