Arcutis Announces Publication of Positive Long-Term Safety and Efficacy Data with ZORYVE® (roflumilast) Cream 0.05% for Treatment of Mild-to-Moderate Atopic Dermatitis in Children Ages 2–5 in Pediatric Dermatology

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- ZORYVE cream 0.05% was safe and well-tolerated, with efficacy that was maintained and improved over time up to 56 weeks of treatment
- Children ages 2-5 who achieved disease clearance and who switched to proactive twice-weekly application sustained disease control for a median duration of ~8 months
- These results further support the Company's focus on expanding options for pediatric populations

WESTLAKE VILLAGE, Calif., March 10, 2026 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced that *Pediatric Dermatology* published data from the Phase 3 open-label extension (INTEGUMENT-OLE) study evaluating once-daily ZORYVE® (roflumilast) cream 0.05% in children aged 2 to 5 years with mild-to-moderate atopic dermatitis. Data from the INTEGUMENT-OLE trial, which supported the FDA approval of ZORYVE cream 0.05% in October 2025, demonstrated that ZORYVE cream 0.05% is safe and well-tolerated, and efficacy was not only maintained but continued to improve with up to 56 weeks of treatment.

Atopic dermatitis is the most common type of eczema, affecting approximately 9.6 million children in the United States. These data expand upon findings from the pivotal four-week Phase 3 trial INTEGUMENT-PED (INterventional Trial EvaluatinG roflUMilast cream for the treatmENt of aTopic dermatitis), which first established the efficacy and safety of ZORYVE cream 0.05% in this pediatric population.

"In my clinical practice, young children with atopic dermatitis struggle with the itchy rash that can cover large portions of their bodies," said Lawrence F. Eichenfield, MD, chief of pediatric and adolescent dermatology at Rady Children's Hospital-San Diego and lead author of the publication. "Providing safe, effective nonsteroidal treatment options for young patients—who can have substantial disease burden but have limited available therapies —remains an important goal in pediatric dermatology. The publication of these data reinforces ZORYVE cream 0.05% as a meaningful, long-term treatment option for children living with atopic dermatitis and their families."

This Phase 3, open-label safety trial was conducted in children aged 2 to 5 years with mild-to-moderate atopic dermatitis who had previously been treated with ZORYVE cream 0.05% or vehicle cream in the preceding four-week INTEGUMENT-PED study. During the 52-week OLE study, all participants (n=562) initially applied ZORYVE cream 0.05% once daily as a monotherapy to all areas of the body impacted by atopic dermatitis, excluding the scalp. Per study protocol, children who achieved clear skin, or a Validated Investigator Global Assessment for atopic dermatitis (vIGA-AD) = 0 at or after Week 4, were transitioned to a proactive twice-weekly (BIW) regimen, and the efficacy results reported in this publication include data from both once-daily and BIW participants.

The primary endpoint of the OLE study was safety. Treatment-Emergent Adverse Events (TEAEs) were reported for 280 (49.8%) participants, and most events were mild (n=139; 24.7%) or moderate (n=125; 22.2%). The most common TEAEs (≥4%) included upper respiratory tract infection in 8.7% of participants, nasopharyngitis in 5.0%, and pyrexia in 5.0%. Gastrointestinal adverse events (AEs) were reported for 4.4% of participants, most commonly vomiting (2.7%) and diarrhea (1.1%). Serious Adverse Events (SAEs) occurred in 18 (3.2%) participants, none of which were considered treatment-related. Overall, 14 of 562 participants (2.5%) experienced treatment-related AEs, and 4 participants (0.7%) experienced application site pain.

Based on investigator-rated local tolerability assessments, ≥97% of study participants had no evidence of local irritation across time points. For caregiver-reported local tolerability assessments, reports of burning or stinging sensations were low, with severe sensations occurring in ≤1.8% of participants at any time point and 0.3% at Week 56. Over the 56-week period, 55 participants attained their 6th birthday and were transitioned to ZORYVE cream 0.15% for at least one application; safety outcomes observed in this subgroup were consistent with the overall study population.

Durable and continuously improving efficacy, assessed via prespecified secondary endpoints, was observed in the study. In participants who completed 56 weeks of treatment (n=377), 63.1% achieved a vIGA-AD score of Clear or Almost Clear (0 or 1) at Week 56. At Week 56, 71.9% of children who continued treatment with ZORYVE cream 0.05% and 76.0% of children who switched from vehicle to ZORYVE cream 0.05% achieved at least a 75% reduction in Eczema Area and Severity Index (EASI-75). Itch improvement, as assessed by caregivers using the Worst Itch Numeric Rating Scale (WI-NRS)—a measure validated in patients aged 12 years and older—showed that 57.9% of children who continued treatment with ZORYVE cream 0.05% and 66.3% of children who switched from vehicle to ZORYVE cream 0.05% achieved a ≥4-point improvement at the end of the study. Efficacy assessments excluded palms, soles, and the scalp.

Children who achieved clear skin (vIGA-AD = 0) at or after Week 4 were transitioned to a proactive twice-weekly application schedule. Of the 170 participants (30.2%) who entered twice-weekly dosing, the median Kaplan-Meier duration of disease control (maintaining vIGA-AD of 'Clear' or 'Almost Clear,' with adequate control of signs and symptoms on the twice-weekly schedule application) was 238 days.

"Atopic dermatitis often begins early in life, during a time when the immune system is developing and the skin is vulnerable. For this young age group, long-term treatment options have historically been limited, making it especially important to have therapies that are both safe and effective," said Patrick Burnett, MD, PhD, FAAD, chief medical officer, Arcutis Biotherapeutics. "The publication of these long-term data reinforces the strong safety profile and durable efficacy of ZORYVE cream 0.05% and highlights our commitment to providing clinicians, families, and young children with

treatment options that can be used confidently over time."

About Atopic Dermatitis
Atopic dermatitis is the most common type of eczema, 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 has unique clinical presentations across the lifespan. The disease typically appears as a red, intensely itchy rash that can occur anywhere on the body. It presents differently in infants, children, and adults. Younger children typically have more widespread atopic dermatitis, including on the face, neck, and areas around the knees and elbows.

Atopic dermatitis is often initially diagnosed during childhood with approximately 90% of people with atopic dermatitis developing symptoms by age 5. Pediatric atopic dermatitis can negatively impact the entire family by significantly disrupting sleep, increasing the risk of skin infections, and leading to developmental and emotional strain for both the child and caregivers.

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."

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.

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.

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 for ZORYVE cream 0.05% to advance the standard of care in atopic dermatitis for pediatric patients aged 2 to 5 years old, and real world treatment results. 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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