Arcutis Completes Enrollment in INTEGUMENT-INFANT Phase 2 Study Evaluating ZORYVE® (roflumilast) Cream 0.05% in Infants with Atopic Dermatitis

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- Investigational ZORYVE cream 0.05% was formulated for the delicate skin of infants and young children with mild to moderate atopic dermatitis
- Topline results anticipated in Q1 2026
- The U.S. FDA approved ZORYVE cream 0.05% for the treatment of mild to moderate atopic dermatitis in children ages 2 to 5 years in October 2025
- Atopic dermatitis impacts 9.6 million children in the U.S., with up to 60% developing symptoms within their first year

WESTLAKE VILLAGE, Calif., Nov. 13, 2025 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced the enrollment of the last subject in the INTEGUMENT-INFANT Phase 2 open-label clinical study, which is evaluating the safety and tolerability of investigational once-daily ZORYVE (roflumilast) cream 0.05% in infants aged 3 months to less than 24 months with mild to moderate atopic dermatitis. ZORYVE cream is a highly selective and potent topical phosphodiesterase-4 (PDE4) inhibitor formulated to address the unique needs of individuals with atopic dermatitis.

“Atopic dermatitis often presents in infancy and can cause significant discomfort from the itch and rash, and even disruption to sleep and social activities, which can negatively impact the affected child and the entire family,” said Patrick Burnett, MD, PhD, FAAD, chief medical officer at Arcutis. “Enrollment in the INTEGUMENT-INFANT study has been brisk, reflecting strong interest from parents seeking an alternative to topical corticosteroids. This clinical milestone represents a significant step in advancing a well-tolerated topical treatment for this vulnerable population, for whom FDA-approved options remain limited. We eagerly anticipate the study results as we continue to develop ZORYVE cream 0.05% as a potential new treatment for pediatric atopic dermatitis in infants as young as three months.”

About the INTEGUMENT-INFANT Study
The INTEGUMENT-INFANT Phase 2, open-label, multicenter study is evaluating the safety and tolerability of ZORYVE cream 0.05% applied once daily over a four-week period in 101 infants aged 3 months to less than 24 months with mild to moderate atopic dermatitis. The study builds upon the earlier Maximal Usage (MUSE) pharmacokinetics trial ARQ-151-105, which also evaluated ZORYVE cream 0.05% in this age group.

Topline results from the study are expected to be reported in Q1 2026.

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 60% of children developing symptoms within their first year. 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 recently 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% as a treatment for pediatric AD patients, including infants from 3 to less than 24 months, and timing of potential clinical 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, 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.

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