Arcutis Announces Positive Topline Results for INTEGUMENT-INFANT Phase 2 Trial of ZORYVE® (roflumilast) Cream 0.05% in Infants with Mild to Moderate Atopic Dermatitis

February 2, 2026

- 58% of participants achieved a 75% improvement in Eczema Area and Severity Index (EASI-75) with ZORYVE cream 0.05% at Week 4
- Investigational ZORYVE cream 0.05% was well tolerated and demonstrated a safety profile consistent with previous studies, with no new safety signals identified through 4 weeks of treatment
- Atopic dermatitis impacts 9.6 million children in the United States; up to 60% of children with atopic dermatitis develop symptoms within their first year
- The Company plans to submit a supplemental New Drug Application (sNDA) for ZORYVE cream 0.05% for this age group in Q2 2026

WESTLAKE VILLAGE, Calif., Feb. 02, 2026 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced positive topline results from the INTEGUMENT-INFANT Phase 2 study evaluating the safety, tolerability, and efficacy of ZORYVE® (roflumilast) cream 0.05% in infants aged 3 months to less than 24 months with atopic dermatitis. ZORYVE cream, a highly selective and potent topical phosphodiesterase 4 (PDE4) inhibitor, was well tolerated with a safety profile consistent with previous ZORYVE clinical trials. Overall, the incidence of adverse events was low, with all being mild to moderate in severity. ZORYVE cream improved the severity of disease and reduced the area of skin affected by atopic dermatitis, with 58% of participants achieving EASI-75 at Week 4.

“Atopic dermatitis is the most common type of eczema and often starts in infancy. For our youngest patients, it’s critical to have therapies that are both safe and effective and that can be used on all body areas, including the face and diaper region,” said Mercedes E Gonzalez, MD, pediatric dermatologist and co-founder of Dermatology360 and INTEGUMENT-INFANT investigator. “These data underscore the potential of investigational ZORYVE cream 0.05% to provide meaningful improvements in the signs and symptoms of atopic dermatitis, while reinforcing its well-established and consistent safety profile.”

The Phase 2 study results reinforce the consistency of the safety and tolerability profile of ZORYVE cream 0.05% already seen in the four-week pivotal INTEGUMENT-PED clinical trial in children ages 2 to 5 years. The most frequently reported adverse events (≥3%; n=101) included: diarrhea, nasopharyngitis, upper respiratory tract infection, and vomiting. Only one trial participant discontinued the study due to an adverse event, and there were no serious adverse events.

“Reaching this clinical development milestone for ZORYVE through the INTEGUMENT -INFANT study underscores our commitment toward providing safe, effective non-steroidal treatment options for even the youngest patients with atopic dermatitis who have substantial disease burden and very limited treatment options today. Based on my experience as a pediatric dermatologist, demonstrating efficacy and tolerability in infants — using a formulation specifically developed with young children suffering from atopic dermatitis in mind—not only advances our development program but gives hope to our patients and their families who are suffering with the burdensome symptoms of atopic dermatitis,” said David Berk, MD, FAAD, vice president of R&D strategy and clinical development at Arcutis. “We want to thank the investigators, caregivers, and children who participated in this study for their partnership and commitment, which make advances like this possible.”

About the INTEGUMENT-INFANT Study
The INTEGUMENT-INFANT Phase 2, open-label, multicenter study evaluated 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.

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 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 U.S. Food and Drug Administration (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. In 2024, ZORYVE cream 0.15% was awarded *Glamour's* Beauty and Wellness Award for "Best Eczema Product." Additionally, the American Academy of Dermatology 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.

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 allow 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.

ZORYVE is for topical use only and not for ophthalmic, oral, or intravaginal use.

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 timing of the submission of the sNDA for ZORYVE cream 0.05%, statements regarding the potential that clinical trial results will translate to real-world use of ZORYVE cream, and the potential for ZORYVE cream to advance the standard of care in atopic dermatitis. 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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