Arcutis Presents New Phase 2 Results in Infants with Atopic Dermatitis in Late-Breaking Session Today at the 2026 American Academy of Dermatology Annual Meeting

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- Investigational ZORYVE® (roflumilast) cream 0.05% was well tolerated with safety findings consistent with prior pediatric experience in the INTEGUMENT program
- ZORYVE cream improved signs and symptoms of mild to moderate atopic dermatitis in infants aged 3 months to less than 24 months over four weeks
- Caregivers reported rapid improvement in itch in as little as 10 minutes in nearly half of infants
- Results from additional studies across the ZORYVE portfolio being presented in three poster presentations

WESTLAKE VILLAGE, Calif. and DENVER, March 28, 2026 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced new data from the INTEGUMENT-INFANT Phase 2 trial demonstrating that ZORYVE® (roflumilast) cream 0.05% reduced signs and symptoms of atopic dermatitis, the most common form of eczema, in infants aged 3 months to less than 24 months with mild to moderate atopic dermatitis. These results build upon the topline results announced last month and further support the potential of investigational ZORYVE cream as a treatment option for this youngest and very vulnerable population. The results were presented today during a late-breaking podium presentation at the 2026 American Academy of Dermatology (AAD) Annual Meeting in Denver, CO.

“Infantile atopic dermatitis presents daily challenges for affected patients and their families, and clinicians have limited topical options to treat it,” said Lawrence F. Eichenfield, MD, of Rady Children’s Hospital San Diego and the University of California San Diego School of Medicine, and presenting author of the INTEGUMENT-INFANT data. “The rashes and itch of eczema result in disrupted sleep and significant distress for both infants and their families. In this Phase 2 study, once-daily ZORYVE cream 0.05% provided meaningful improvements in severity of the signs and symptoms of disease over four weeks, with caregivers reporting rapid relief of itch in as little as 10 minutes. The study results show that ZORYVE cream was effective with a safe and well-tolerated profile in infants down to 3 months of age.”

The INTEGUMENT-INFANT open-label trial evaluated the safety and tolerability of once-daily ZORYVE cream 0.05% in infants (n=101) aged 3 months to less than 24 months with mild to moderate atopic dermatitis over four weeks. 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 aged 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. In addition, based on investigator-rated local tolerability assessments, ≥97.9% of infants experienced no application site irritation throughout the four weeks.

In new data released today, among participants who completed four weeks of treatment (n=96), 34.4% achieved Validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD) success (defined as a score of 0 (Clear) or 1 (Almost Clear) with a ≥2-grade improvement). In addition, 49% of infants achieved a vIGA-AD score of Clear or Almost Clear (0 or 1) at Week 4, and 24% already at Week 2. For those infants with at least mild scalp involvement at baseline (n=40), 67.5% achieved vIGA-scalp success (scalp Clear or Almost Clear (0 or 1) with ≥2-point improvement from baseline) at Week 4. As previously reported, 58.3% of infants achieved at least a 75% reduction in Eczema Area and Severity Index (EASI-75) at Week 4 (n=96), and 34% of infants at Week 2 (n=100).

In addition, caregivers reported improvement in itch. Itch improvement, as assessed by caregivers using the Worst Scratch Itch Numeric Rating Scale (WSI-NRS)—a measure validated in patients aged 6 months to 6 years—showed that 72.7% of infants achieved WSI-NRS success, defined as a ≥4-point improvement at the end of the study, at Week 4 (n=77) and 60.3% at Week 2 (n=73). Furthermore, 66.7% of infants achieved at least a 25% improvement from baseline in pruritus based on the Dynamic Pruritus Scale (DPS-25) at four hours (n=87), 58.6% at one hour (n=87), and 46.6% at 10 minutes (n=88).

“Atopic dermatitis often begins in the first months of life, underscoring the need for therapies that are both safe and effective and can be used anywhere on the body for these youngest of patients,” said Patrick Burnett, MD, PhD, FAAD, chief medical officer, Arcutis. “Findings from the INTEGUMENT-INFANT study add important clinical evidence for investigational ZORYVE cream 0.05% in infants 3 to <24 months, including demonstrating that ZORYVE cream is effective as measured by multiple clinical endpoints, and well-tolerated, with minimal to no evidence of irritation at the application site. Arcutis is committed to advancing effective and well-tolerated non-steroidal treatment options for patients with atopic dermatitis, especially for this vulnerable population.”

These data will support Arcutis’ planned supplemental New Drug Application for ZORYVE cream 0.05% in infants aged 3 months to less than 24 months, which the Company expects to submit in the second quarter of 2026. The findings further expand the body of evidence supporting ZORYVE as an advanced targeted topical therapy across age groups, body areas, and disease severities.

Key Results from Additional Studies Supporting the ZORYVE Portfolio Presented in Posters:

New results from the **INTEGUMENT-OLE Phase 3 trial** (poster presentation) demonstrate that ZORYVE cream 0.05% was well tolerated and provided durable improvements in caregiver-reported outcomes that are maintained over the long term in children aged 2 to 5 years with mild to

moderate atopic dermatitis. These follow the recent publication of the full results of INTEGUMENT-OLE published in the journal *Pediatric Dermatology* earlier this month.

Findings from a **STRATUM Phase 3 trial** subgroup analysis (e-poster) show that ZORYVE foam 0.3% was well tolerated and improved signs and symptoms of seborrheic dermatitis through 8 weeks of treatment in individuals with seborrheic dermatitis including those with face and/or scalp involvement. The analysis supports ZORYVE foam 0.3% as a suitable potential treatment of anatomical areas where topical steroid use is limited by safety considerations, such as the face.

Further analysis from the previously published **Phase 3 DERMIS-1/2 and ARRECTOR trials** (e-poster) found that ZORYVE cream 0.3% and foam 0.3% improved psoriasis severity, reducing Psoriasis Area and Severity Index (PASI) total and component scores more than vehicle cream or vehicle foam. Mean improvements in psoriasis were reported with ZORYVE cream and foam across body regions: head and neck, trunk, and upper and lower extremities. These results confirm that both ZORYVE cream 0.3% and foam 0.3% provide consistent benefit across body regions affected by psoriasis, offering a treatment alternative to commonly used topical steroids.

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 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.

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.

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 FDA approval of ZORYVE cream 0.05% for infants 3 to <24 months, and the potential for ZORYVE cream and ZORYVE foam to advance the standard of care in atopic dermatitis, plaque psoriasis, seborrheic dermatitis, and other inflammatory dermatological conditions. 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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