Arcutis Presents New Caregiver-Reported Outcomes Data Supporting ZORYVE® (roflumilast) Cream 0.05% for Mild to Moderate Atopic Dermatitis in Infants Down to 3 Months at the ACAAI Annual Scientific Meeting

November 13, 2026

- New INTEGUMENT-INFANT trial results demonstrate improvements in itch, reductions in symptoms, and improvements in quality of life for infants with atopic dermatitis and their families
- Findings further support investigational ZORYVE cream 0.05% to help address unmet needs in infants aged 3 to <24 months
- 60% of children develop atopic dermatitis symptoms within their first year of life

WESTLAKE VILLAGE, Calif., Nov. 13, 2026 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced new caregiver-reported outcomes data from the INTEGUMENT-INFANT trial supporting ZORYVE® (roflumilast) cream 0.05% in the treatment of infants with mild to moderate atopic dermatitis ages 3-24 months presented at the American College of Allergy, Asthma & Immunology's (ACAAI) Annual Scientific Meeting, taking place Nov. 12-16 in Phoenix, Arizona.

“Managing atopic dermatitis in infants can be particularly challenging, especially given the lifelong, chronic nature of the disease and the fact that the skin barrier and immune system are still developing. Today, there are very limited approved treatment options for infants, especially steroid-free options, leaving healthcare providers and caregivers with too few options,” said Mark Boguniewicz, MD, professor, Department of Pediatrics, National Jewish Health and University of Colorado School of Medicine. “These new findings showed that alongside having a generally safe and well-tolerated profile, ZORYVE demonstrated improvements in the signs and symptoms of atopic dermatitis, as well as quality of life measurements, as reported by caregivers. These results underscore the importance of expanding treatment options to address the unique needs of this vulnerable population.”

Atopic dermatitis is the most common form of eczema with 60% of children developing symptoms within their first year of life. The combination of itching and associated sleep disturbance for infants with atopic dermatitis, as well as the financial and emotional stress of treatment experienced by caregivers, results in significant disease burden.

“These new caregiver-reported outcomes showing improvement in both symptoms and quality of life measures add to the growing body of clinical evidence supporting the potential of ZORYVE cream 0.05% to address a significant unmet need for infants with atopic dermatitis and their families,” said Patrick Burnett, MD, PhD, FAAD, chief medical officer of Arcutis. “Together with previously reported results, these findings reinforce the potential of ZORYVE to provide a well-tolerated, steroid-free treatment option for managing the burdensome symptoms of atopic dermatitis that can begin in infancy. With our supplemental New Drug Application currently under FDA review, we look forward to the possibility of bringing this important new treatment option to infants as young as 3 months of age, if approved.”

A total of 101 infants were enrolled in the INTEGUMENT-INFANT trial evaluating ZORYVE cream 0.05%. Caregiver-reported outcomes demonstrated improvements in itch, atopic dermatitis symptoms, and quality of life for infants and their families.

Key findings include:

- **Favorable tolerability:** ZORYVE cream 0.05% was well tolerated, with no serious adverse events (SAEs) or severe treatment-emergent adverse events (TEAEs) reported (n=101). At least 97.9% of infants had no evidence of investigator-rated application-site irritation across assessment timepoints.
- **Improvements in itch:** Caregivers reported improvements in itch as early as 10 minutes after the first application, with 46.6% of infants achieving a ≥25% improvement in itch (Dynamic Pruritus Score–25; n=88), increasing to 66.7% of infants at 4 hours (n=87). Additionally, 10.4% of infants achieved WSI-NRS success at 24 hours (n=77), increasing to 72.7% of infants at the last assessment (n=77).
- **Improvements in atopic dermatitis symptoms:** Caregivers reported reductions in the frequency of symptoms such as bleeding, cracking, dryness, flaking, itching, weeping, and sleep loss, as measured by the Patient-Oriented Eczema Measure (POEM), which assesses the frequency of eczema symptoms over the previous week, with scores ranging from 0 to 28 (higher scores indicating greater disease severity). Mean POEM scores decreased from 14.5 at baseline (moderate severity) to 7.9 at Week 2 (n=100) and 6.5 at Week 4 (n=96), reflecting a shift from moderate to mild disease severity.
- **Improvements in infant quality of life and family impact:** Caregivers reported improvements in infant quality of life, as measured by the Infants' Dermatitis Quality of Life Index (IDQoL), and improvements in family quality of life, as measured by the Dermatitis Family Impact (DFI) questionnaire. Improvements with investigational ZORYVE cream 0.05% were reported across factors including daily activities, sleep, emotional well-being, family activities, and relationships.

ePoster presentation details are as follows:

- **R378:** Caregiver-Reported Outcomes With Roflumilast Cream in Infants Aged 3 to Less Than 24 Months: INTEGUMENT-INFANT
- **Date & Time:** Friday, Nov. 13 at 3:30 p.m. MST
- **Location:** North Halls (4-6) Lower Level, Monitor 25

ZORYVE cream 0.05% is approved in the United States for the topical treatment of mild to moderate atopic dermatitis in children aged 2-5 years. A supplemental New Drug Application (sNDA) for ZORYVE cream 0.05% to expand the indication for the topical treatment of mild to moderate atopic dermatitis to include infants aged 3 to 24 months is under review, with a Prescription Drug User Fee Act (PDUFA) target action date of February 23, 2027.

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. The disease typically appears as a red, intensely itchy rash that can occur anywhere on the body. Younger children may have especially widespread atopic dermatitis, including on the face and neck.

Atopic dermatitis is often initially diagnosed during childhood with approximately 90% of people with atopic dermatitis developing symptoms by age 5 and up to 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 (eczema), 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, including three from major beauty magazines: *Allure*'s "2025 Best of Beauty Breakthrough Award," *Glamour's* 2024 Beauty and Wellness Award for "Best Eczema Product," and most recently, *Marie Claire's* "2026 Best Prescription Skin Solution" Award.

In addition, the National Psoriasis Foundation honored ZORYVE with its Seal of Recognition and the American Academy of Dermatology (AAD) issued a strong recommendation for the use of ZORYVE cream 0.15% in adults with mild to moderate atopic dermatitis and ZORYVE cream 0.05% for children aged 2-5 years, as well as a strong recommendation for ZORYVE cream 0.15% for children aged 6 years and older with mild to moderate atopic dermatitis in its first-ever pediatric atopic dermatitis guidelines.

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 2 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.

About Arcutis
Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a commercial-stage medical dermatology company delivering meaningful innovation to address the needs of individuals living with chronic inflammatory skin diseases. Over the past decade, Arcutis has successfully developed a robust portfolio of advanced targeted topicals approved to treat three major inflammatory skin diseases, driven by a commitment to solving the most persistent patient challenges in dermatology. Arcutis' unique dermatology development platform, built on established scientific pathways and coupled with deep clinical dermatology and commercial expertise, enables us to efficiently develop, scale, and deliver our differentiated therapies while advancing a growing

pipeline across 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 FDA approval of ZORYVE cream 0.05% for the treatment of infants with mild to moderate atopic dermatitis ages 3-24 months, its potential to advance the standard of care in AD, and clinical trial results translating into real world results, including among others, tolerability, itch and quality of life. 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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