



Arcutis Submits Supplemental New Drug Application to the FDA for ZORYVE® (roflumilast) Cream 0.05% to Expand Indication for Treatment of Atopic Dermatitis to Infants Down to 3 Months

April 27, 2026

- Submission supported by data from INTEGUMENT-INFANT Phase 2 open-label study in infants aged 3 months to less than 24 months with mild to moderate atopic dermatitis
- Once-daily ZORYVE cream was well tolerated with a safety profile consistent with that in older children and adults
- Atopic dermatitis impacts 1 million children under the age of 2 in the United States
- Only one other FDA-approved topical non-steroidal anti-inflammatory agent available for this vulnerable population

WESTLAKE VILLAGE, Calif., April 27, 2026 (GLOBE NEWSWIRE) -- [Arcutis Biotherapeutics, Inc.](#) (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced the submission of a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) seeking to expand the indication for ZORYVE® (roflumilast) cream 0.05% to include the topical treatment of mild to moderate atopic dermatitis in infants down to 3 months.

"Atopic dermatitis often begins within the first year of life, yet treatment options for infants are extremely limited. Parents and caregivers are often faced with difficult decisions around managing these symptoms, including concerns about the long-term use of topical steroids," said Mercedes E. Gonzalez, MD, medical director of Pediatric Skin Research, LLC and INTEGUMENT-INFANT clinical trial investigator. "Because their immune system and skin barrier are still developing, infants are particularly vulnerable to the burdensome symptoms of atopic dermatitis, including visible disease and intense itch that can disrupt sleep and significantly impact both infants and their caregivers. Safe and effective long-term therapies suitable for use anywhere on the body, including sensitive regions such as the face and skin folds, remain an important unmet need for infants with atopic dermatitis. If approved, ZORYVE cream 0.05% could offer a much-needed, non-steroidal treatment option developed specifically for very young children, including infants."

Atopic dermatitis is the most common form of eczema and frequently presents during infancy, contributing to significant child and caregiver burden and impaired quality of life. In infants, atopic dermatitis can have more widespread presentation on the body and infants demonstrate a higher body surface area-to-body mass ratio, which may increase the risk of side effects from topical treatment.

"This sNDA submission represents an important milestone in our effort to expand treatment options for infants as young as 3 months living with atopic dermatitis, an age group with very limited treatment options today," said Frank Watanabe, president and CEO of Arcutis. "If approved, investigational ZORYVE cream 0.05% could offer an effective and well-tolerated treatment option suitable for long-term use, helping infants and their families maintain clear skin and limit cumulative topical steroid exposure. This potential age expansion supports our strategy to broaden ZORYVE's reach and reinforces its role as a foundational therapy across age groups."

The sNDA is supported by positive results from a Phase 1 open-label pharmacokinetic (PK) trial and a Phase 2 open-label trial (INTEGUMENT-INFANT), both of which evaluated once-daily ZORYVE cream 0.05% in infants aged 3 months to less than 24 months with mild to moderate atopic dermatitis. The Phase 1 study enrolled 19 infants and demonstrated PK, safety and efficacy profiles over four weeks that were consistent with those from prior pediatric atopic dermatitis studies in older children. The INTEGUMENT-INFANT study enrolled 101 infants and assessed safety, tolerability, and efficacy over four weeks, and in this study, ZORYVE cream 0.05% was well tolerated in infants. The safety and tolerability profile observed in the INTEGUMENT-INFANT study was consistent with prior pediatric experience across the INTEGUMENT program. The most frequently reported adverse events included diarrhea, nasopharyngitis, upper respiratory tract infection, and vomiting.

Among infants who completed four weeks of treatment in INTEGUMENT-INFANT (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 from baseline. In addition, 49% of infants achieved a vIGA-AD score of Clear or Almost Clear at Week 4, with 24% achieving vIGA-AD score of Clear or Almost Clear at Week 2, and improvements were observed as early as Week 1. Among infants with at least mild scalp involvement at baseline, 67.5% (27/40) achieved vIGA-scalp success at Week 4. In the study, 58.3% of infants achieved at least a 75% reduction from baseline in Eczema Area and Severity Index (EASI-75) at Week 4, with 34% achieving EASI-75 at Week 2.

Caregiver-reported assessments also demonstrated rapid improvement in itch, with 72.7% of infants achieving Worst Scratch Itch Numeric Rating Scale (WSI-NRS) success, defined as a ≥ 4 -point improvement at Week 4 (end of study, 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).

ZORYVE cream 0.05% was intentionally formulated for atopic dermatitis and is suitable for children and infants with atopic dermatitis whose immune system and skin barrier are still developing. The 0.05% dose was specifically selected for children ≤ 5 years of age, in part based on the understanding of the skin barrier dysfunction associated with atopic dermatitis, which is especially important because the skin of infants and younger children is still developing. ZORYVE cream 0.05% is a once-daily, steroid-free, non-greasy topical treatment that does not contain sensitizing excipients or irritants such as propylene glycol, polyethylene glycol, ethanol, or fragrances. ZORYVE cream 0.05% is already approved for the treatment of mild to moderate atopic dermatitis in patients aged 2-5 years.

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, seborrheic dermatitis, and plaque psoriasis. ZORYVE cream 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, as well as a strong recommendation for the use of ZORYVE cream 0.05% for children aged 2-5 years and ZORYVE cream 0.15% for children aged 6 years and older with mild to moderate atopic dermatitis from the AAD's first-ever pediatric atopic dermatitis guidelines published in April 2026. In 2024, ZORYVE cream 0.15% was awarded *Glamour's* Beauty and Wellness Award for "Best Eczema Product."

INDICATION

ZORYVE cream, 0.05%, is indicated for topical treatment of mild to moderate atopic dermatitis in pediatric patients 2 to 5 years of age.

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 ($\geq 1\%$) 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%).

Please see [full Prescribing Information for ZORYVE cream](#).

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](#).

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 aged 3 months to less than 24 months with mild to moderate atopic dermatitis, 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, 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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