FDA Accepts Supplemental New Drug Application for Arcutis' ZORYVE® (roflumilast) Cream 0.05% for the Treatment of Mild to Moderate Atopic Dermatitis in Infants Down to 3 Months

July 8, 2026

- FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of February 23, 2027
- Application supported by positive results from Phase 2 open-label INTEGUMENT-INFANT study and Phase 1 open-label pharmacokinetic (PK) study
- 1 million children under the age of 2 are treated topically for atopic dermatitis in the United States, representing 10% of all adults and children treated topically for atopic dermatitis

WESTLAKE VILLAGE, Calif., July 08, 2026 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced that the U.S. Food and Drug Administration (FDA) has accepted its supplemental New Drug Application (sNDA) for ZORYVE® (roflumilast) 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. The FDA has set a PDUFA target action date of February 23, 2027.

"Infants with atopic dermatitis are particularly vulnerable to burdensome symptoms such as intense itch and sleep disruption, which can impact the whole family. Managing these symptoms can be particularly challenging for parents and caregivers due to the very limited FDA-approved treatment options as well as concerns about the use of topical steroids on infants whose skin barrier and immune system are still developing," said Lawrence F. Eichenfield, MD, of Rady Children's Hospital San Diego and the University of California San Diego School of Medicine and an INTEGUMENT-INFANT clinical trial investigator. "There is a significant unmet need in this population for therapies that can be used anywhere on the body for any duration of time, including on sensitive areas such as the face and skin folds. If approved, ZORYVE cream 0.05% could provide clinicians and caregivers with an important new steroid-free treatment option that was specifically developed for infants and very young children."

Atopic dermatitis is the most common form of eczema and often begins during infancy, contributing to significant burden for both infants and caregivers due to the chronic cycling of itching and scratching that can lead to discomfort and disruptions in sleep.

"This sNDA acceptance underscores the gap in approved treatments for very young children with atopic dermatitis," said Frank Watanabe, president and CEO of Arcutis. "If approved, investigational ZORYVE cream 0.05% would be the first once-daily advanced targeted topical treatment for this especially vulnerable patient population and would provide a much-needed non-steroidal treatment option that effectively reduces symptoms of atopic dermatitis like itch quickly, and with a safe and well-tolerated profile. This expanded indication would further reinforce ZORYVE's potential to serve as a foundational treatment option for individuals with atopic dermatitis from infancy through adulthood."

The sNDA is supported by positive results from the Phase 2 open-label INTEGUMENT-INFANT study, as well as a Phase 1 open-label pharmacokinetic (PK) study, 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 INTEGUMENT-INFANT study enrolled 101 infants and assessed safety, tolerability, and exploratory efficacy over 4 weeks. The Phase 1 study enrolled 19 infants. Both studies demonstrated PK, safety, and efficacy profiles over 4 weeks that were consistent with those from prior atopic dermatitis studies in children 2 to 5 years of age treated with ZORYVE cream 0.05%.

Key trial results include:

- ZORYVE cream 0.05% showed a well-tolerated, safe profile consistent with previous studies, with no new safety signals identified through 4 weeks of treatment. The most frequently reported adverse events included diarrhea, nasopharyngitis, upper respiratory tract infection, and vomiting.
- ZORYVE cream 0.05% demonstrated rapid disease clearance through 4 weeks of treatment.
    - Among infants who completed 4 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.
    - 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.
    - Among infants with at least mild scalp involvement at baseline, 67.5% (27/40) achieved vIGA-scalp success at Week 4.
- Caregivers also reported rapid improvements in itch, with 46.6% of infants achieving at least a 25% improvement from baseline in pruritus within 10 minutes after application, as assessed by caregivers, based on the Dynamic Pruritus Scale (DPS-25) (n=88).

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 children 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 adults with mild to moderate atopic dermatitis, 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. In 2024, ZORYVE cream 0.15% was awarded *Glamour's* Beauty and Wellness Award for "Best Eczema Product."

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.

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

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%, and the potential for ZORYVE cream and ZORYVE foam to advance the standard of care in AD, plaque psoriasis 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, 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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