Arcutis Enrolls First Child in INTEGUMENT-INFANT Evaluating ZORYVE® (roflumilast) Cream 0.05% in Infants with Atopic Dermatitis

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- Four-week Phase 2 study to evaluate investigational, once-daily ZORYVE .05% in infants as young as 3 months to less than 2 years with atopic dermatitis
- 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

WESTLAKE VILLAGE, Calif., June 10, 2025 (GLOBE NEWSWIRE) -- **Arcutis Biotherapeutics, Inc.** (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced that the first child has been enrolled in a Phase 2 open-label study, INTEGUMENT-INFANT, evaluating the safety and tolerability of investigational ZORYVE (roflumilast) cream 0.05% in infants aged 3 months to less than 24 months with atopic dermatitis (AD) applied once daily over a four-week period. ZORYVE cream is a highly potent and selective phosphodiesterase-4 (PDE4) inhibitor formulated for topical use.

“AD is a lifelong chronic condition in children that can 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,” said Patrick Burnett, MD, PhD, FAAD, chief medical officer at Arcutis. “Despite the high prevalence, early onset, and serious impact of AD, there are very few topical or systemic therapies approved for infants, making new clinical research for tolerable and effective treatments that can be used over a lifetime and can reduce or replace steroids, critically important for this age group. Enrolling the first child in this study is a meaningful step forward and builds on our mission to address unmet needs in pediatric dermatology.”

About INTEGUMENT-INFANT
This Phase 2, open-label, multicenter study will enroll infants aged 3 months to less than 2 years with mild to moderate AD involving at least 3% body surface area. The study’s primary objective is to evaluate the safety and tolerability of roflumilast cream 0.05% applied once daily over four weeks in this age group. This study builds on the successful results of the ARQ-151-105 (MUSE) study, which evaluated roflumilast cream 0.05% in infants aged 3 months to 24 months with AD.

About Atopic Dermatitis
AD 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.

AD, also known as eczema, is one of the most common chronic inflammatory skin conditions in infants and children, with approximately 9.6 million children diagnosed in the United States. Studies estimate that up to 60% of children with AD develop symptoms within their first year, often manifesting as red, scaly patches on the cheeks, chin, and scalp.

About ZORYVE (roflumilast)
ZORYVE is the first and only branded topical therapy for three major inflammatory dermatoses — atopic dermatitis, seborrheic dermatitis, and plaque psoriasis. ZORYVE is a next generation topical PDE4 inhibitor. PDE4, an established target in dermatology, is an intracellular enzyme that increases the production of pro-inflammatory mediators and decreases production of anti-inflammatory mediators.

ZORYVE® (roflumilast) cream 0.3% is approved by the Food and Drug Administration (FDA) for the topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older. ZORYVE (roflumilast) cream 0.15% is approved by the FDA for the topical treatment of mild to moderate atopic dermatitis in patients 6 years of age and older. In 2024, ZORYVE cream 0.15% was awarded *Glamour’s* Beauty and Wellness Award for “Eczema Product.” ZORYVE (roflumilast) topical foam 0.3% is uniquely formulated for use anywhere on the body, including hair-bearing areas, and is indicated for treatment of plaque psoriasis of the scalp and body in patients 12 years of age and older, as well as seborrheic dermatitis in patients 9 years of age and older.

Investigational ZORYVE (roflumilast) cream 0.05% for the topical treatment of mild to moderate AD in children 2 years to 5 years old is under review by the FDA with a Prescription Drug User Fee Act (PDUFA) target action date of October 13, 2025.

INDICATIONS
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.

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 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).

Flammability: The propellants in ZORYVE foam are flammable. Avoid fire, flame, and smoking during and immediately following application.

The most common adverse reactions (≥1%) for ZORYVE foam 0.3% for plaque psoriasis include headache (3.1%), diarrhea (2.5%), nausea (1.7%), and nasopharyngitis (1.3%).

The most common adverse reactions (≥1%) for ZORYVE foam 0.3% for seborrheic dermatitis include nasopharyngitis (1.5%), nausea (1.3%), and headache (1.1%).

The most common adverse reactions (≥1%) for ZORYVE cream 0.3% for plaque psoriasis include 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 (≥1%) for ZORYVE cream 0.15% for atopic dermatitis include 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 and full Prescribing Information for ZORYVE foam.

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 invent differentiated therapies against biologically validated targets, and has produced a robust pipeline with multiple follow-on clinical programs for a range of inflammatory dermatological conditions including atopic dermatitis and alopecia areata. 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 for ZORYVE cream 0.05% as a treatment for AD in infants. 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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