Arcutis Begins Enrolling Phase 3 Study Evaluating ZORYVE® (roflumilast) Cream 0.3% in Moderate to Severe Atopic Dermatitis

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- New INTEGUMENT-3 study to evaluate efficacy, safety, and tolerability of investigational ZORYVE® cream 0.3% in individuals with moderate to severe atopic dermatitis
- Study aims to expand once-daily ZORYVE cream treatment to individuals with moderate to severe atopic dermatitis
- Builds on existing evidence of ZORYVE cream 0.15% for individuals ages 6 and older and ZORYVE cream 0.05% for children ages 2 to 5 with mild to moderate atopic dermatitis

WESTLAKE VILLAGE, Calif., Nov. 05, 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 first participant has been enrolled in a Phase 3, double-blind, randomized, vehicle-controlled study, INTEGUMENT-3. The study is designed to evaluate the efficacy, safety, and tolerability of once-daily ZORYVE® (roflumilast) cream 0.3% for the treatment of individuals ages 6 and older with moderate to severe atopic dermatitis.

“ZORYVE cream has an established efficacy and safety profile in mild to moderate atopic dermatitis, and we see an opportunity to bring the benefits of this innovative treatment to more people living with the disease by evaluating the higher concentration of ZORYVE cream 0.3% in individuals with more severe atopic dermatitis,” said Patrick Burnett, MD, PhD, FAAD, chief medical officer at Arcutis. “Despite advances in treatment, many people with moderate to severe atopic dermatitis continue to experience significant disease burden and are in need of additional treatment options. The initiation of INTEGUMENT-3 marks an important step towards expanding the indication of ZORYVE to fill this gap.”

About INTEGUMENT-3
INTEGUMENT-3 (ARQ-151-323) is a Phase 3, multicenter, randomized, double-blind, vehicle-controlled study evaluating the efficacy, safety, and tolerability of once-daily ZORYVE cream 0.3% in children, adolescents, and adults 6 years of age and older with moderate to severe atopic dermatitis.

Approximately 415 participants aged 6 years and older with moderate to severe atopic dermatitis (validated Investigator Global Assessment for Atopic Dermatitis [vIGA-AD] score of 3 or 4, EASI ≥5, and BSA 3%-30%) will be randomized in a 2:1 ratio to receive either ZORYVE cream 0.3% or matching vehicle cream once daily for 4 weeks during the double-blind treatment period. The primary objective of the study is to assess the safety and efficacy of ZORYVE cream 0.3% compared with vehicle cream administered once daily for 4 weeks in participants aged 6 years and older with moderate to severe atopic dermatitis. A secondary objective is to assess the long-term safety and efficacy of ZORYVE cream 0.3% administered once daily for up to 52 weeks in this patient population.

Participants who complete the double-blind treatment period will be eligible to enter a 48-week open-label extension period, during which all participants will receive once-daily ZORYVE cream 0.3%. The open-label extension is designed to evaluate the long-term safety, tolerability, and efficacy of ZORYVE cream 0.3% up to 52 weeks.

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.

Atopic dermatitis is often characterized as mild to moderate and moderate to severe. Severe eczema can come with additional complications beyond itchy skin and rashes, such as infections that can lead to hospitalization if left untreated.

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 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.

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 of ZORYVE cream 0.3% 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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