Arcutis to Highlight Data from Phase 3 Trials for Scalp and Body Psoriasis and Atopic Dermatitis at the 83rd American Academy of Dermatology Meeting

March 7, 2025

- Data demonstrated favorable safety and local tolerability of ZORYVE® (roflumilast) cream 0.15% in adults and children with atopic dermatitis (AD) with prior inadequate response, intolerance, and contraindications to topical treatments
- New patient reported outcome data for investigational ZORYVE® (roflumilast) foam 0.3% demonstrated favorable efficacy, safety, and local tolerability data in scalp and body psoriasis
- In the United States, AD affects approximately 26 million adults and children and psoriasis affects approximately 9 million adults and children, with more than half experiencing involvement of the scalp

WESTLAKE VILLAGE, Calif. and ORLANDO, Fla., March 07, 2025 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced new data from two posters shared at the 2025 American Academy of Dermatology Annual Meeting (AAD).

The first poster presentation details the positive efficacy, patient reported outcomes, and tolerability for the use of once-daily ZORYVE cream 0.15% in adults and children 6 years and older with mild to moderate AD from the INTEGUMENT 1-2 trials (n=1,337) who reported a prior inadequate response, intolerance or contraindication to topical corticosteroids (TCS; 60.8%), topical calcineurin inhibitors (TCI; 18.1%), or crisaborole (7.3%). At all timepoints assessed during the four-week trial, more than 91% of participants reported no or mild sensation at the application site and investigators reported no irritation or minimal erythema (redness) in ≥ 97% of participants in these subgroups. Improvement in AD was observed across multiple efficacy endpoints and safety was consistent with the overall study population.

A second poster presentation shares results from the Phase 3 ARRECTOR trial that outlines improvements in patient-reported outcomes with investigational ZORYVE foam 0.3% compared with vehicle in adults and children aged 12 or older with psoriasis of the scalp and body. ZORYVE foam significantly improved quality of life across the 23-component Scalpdex assessment throughout the eight-week study period. Individuals reported an improvement in symptoms as well as a reduction in how psoriasis impacted their daily life (e.g., embarrassment, stress, affecting clothing choices, or hair styles).

“While topical therapies are the first line of therapy for millions of people with atopic dermatitis, there are many who are contraindicated or have an inadequate or intolerant response to topical therapies, which have previously been considered the standard of care. These data add to the large body of evidence that highlights the effectiveness, safety, and tolerability of ZORYVE cream 0.15% across diverse patient types, making it a suitable targeted topical and alternative to steroids for adults and children with atopic dermatitis,” said Patrick Burnett, MD, PhD, FAAD, chief medical officer at Arcutis. “In addition, the patient reported outcome data being shared at AAD underscores our team’s commitment to finding meaningful innovations for immuno-dermatologic conditions like psoriasis that can have a significant physical and emotional impact on the individuals that live with these chronic conditions and their caregivers.”

The posters will be available electronically during the meeting in the exhibition poster hall beginning Friday, March 7, 2025.

Pooled Safety and Local Tolerability of Roflumilast Cream 0.15% from the INTEGUMENT-1 and INTEGUMENT-2 Phase 3 Trials of Patients With Atopic Dermatitis: Subgroup Analysis of Patients With Prior Inadequate Response, Intolerance, and/or Contraindications to Topical Treatments
Simpson, E et al.
Poster Number 62155

Roflumilast Foam 0.3% in Patients With Scalp and Body Psoriasis: Improvements in Patient-Reported Outcomes (ARRECTOR)
Gooderham, M et al.
Poster Number 62151

About ZORYVE (roflumilast)
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 U.S. 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 AD 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) cream 0.05% is under review for the treatment of AD in children ages 2 to 5 by the FDA, with a Prescription Drug User Fee Act (PDUFA) target action date of October 13, 2025. Another formulation of ZORYVE, ZORYVE (roflumilast) topical foam, 0.3%, is indicated for treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older. ZORYVE foam is under review for the treatment of scalp and body psoriasis by the FDA with a PDUFA target action date of May 22, 2025.

INDICATIONS
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.

ZORYVE 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 (≥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%).

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%).

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 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 including three FDA approved products that harness our unique dermatology development platform coupled with our dermatology expertise to build differentiated therapies against biologically validated targets. Arcutis' dermatology development platform includes a robust pipeline with multiple clinical programs for a range of inflammatory dermatological conditions including scalp and body psoriasis, AD, 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 of ZORYVE foam and regulatory timing for FDA approval based on the PDUFA for the treatment of scalp and body psoriasis, the potential for clinical results for ZORYVE foam and ZORYVE cream to translate into real-world results, 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, 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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