Arcutis to Present Two Posters at the 83rd American Academy of Dermatology Annual Meeting

February 28, 2025

- One poster will share pooled INTEGUMENT data of ZORYVE® (roflumilast) cream 0.15% in atopic dermatitis (AD) in patients with prior inadequate response, intolerance, and/or contraindications to topical treatments including topical steroids
- Second poster will highlight improvements in patient-related outcomes with ZORYVE® (roflumilast) foam 0.3% in psoriasis of the scalp and body

WESTLAKE VILLAGE, Calif., Feb. 28, 2025 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced that it will present two posters at the 2025 American Academy of Dermatology (AAD) annual meeting which will take place in Orlando, FL, from March 7 – 11, 2025.

The Company will present data from two Phase 3 trials (INTEGUMENT-1 and -2) demonstrating pooled safety and local tolerability of roflumilast cream 0.15% in adults and children down to age six with AD who had prior inadequate response, intolerance, and/or contraindications to topical treatments including topical steroids. A second presentation will spotlight data from its Phase 3 ARRECTOR trial demonstrating significant improvements in patient-related outcomes with roflumilast foam 0.3% in individuals older than 12 years with psoriasis of the scalp and body.

“Highlighting additional data from our clinical development program for ZORYVE foam in scalp and body psoriasis and ZORYVE cream in atopic dermatitis reinforces the strong need for well-tolerated treatments among diverse patient populations, including those intolerant to steroids or who have had an inadequate response,” said Patrick Burnett, MD, PhD, FAAD, chief medical officer at Arcutis. “We are confident that these treatments have the potential to positively impact individuals with chronic inflammatory skin conditions.”

Medical Education Opportunity
Arcutis is proud to support Dr. Candrice Heath of the Heath Health Foundation for Education and Research by hosting two experiential learning sessions at its booth focused on Culturally Conscious Dermatology™. Attendees will have the opportunity to learn about culturally sensitive dermatological care and tips for performing scalp exams.

Dates and Times:
Friday, March 7 at 3:00 PM EST
Saturday, March 8 at 2:30 PM EST
Booth: 1361

Poster Presentations
The following posters will be available electronically at the conference 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)
Roflumilast cream is a next-generation topical phosphodiesterase-4 (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. Roflumilast cream 0.3% (ZORYVE®) 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. Roflumilast cream 0.15% (ZORYVE®) 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.” 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 for the treatment of scalp and body psoriasis is under review by the FDA with a Prescription Drug User Fee Act 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%).

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 https://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.

Contacts:
Media
Amanda Sheldon, Head of Corporate Communications
media@arcutis.com

Investors
Latha Vairavan, Vice President, Finance and Corporate Controller
ir@arcutis.com