Arcutis Presents Positive Patient-Reported Outcome Data for ZORYVE® (Roflumilast) Cream 0.15% in Atopic Dermatitis at American College of Allergy, Asthma and Immunology 2024 Annual Scientific Meeting

October 24, 2024

- New patient-reported outcome data from INTEGUMENT-1 and -2 demonstrate that ZORYVE cream 0.15% rapidly decreased the impact of atopic dermatitis (AD), including sleep loss and daily activities, on patients and families
- ZORYVE cream 0.15% resulted in significant improvements across all efficacy endpoints, including validated Investigator Global Assessment-Atopic Dermatitis (vIGA-AD) Success and rapid itch reduction within 24-hours of first application
- Data presented as an oral presentation at the American College of Allergy, Asthma and Immunology (ACAAI) 2024 Annual Scientific Meeting

WESTLAKE VILLAGE, Calif., Oct. 24, 2024 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced new patient-reported outcome data demonstrating that ZORYVE cream 0.15% improved the impact of AD on patients, families, and caregivers. These results, along with efficacy, safety, and tolerability data from Phase 3 INTEGUMENT-1 and -2, will be shared in an oral presentation at the ACAAI 2024 Annual Scientific Meeting held October 24-28, 2024, in Boston, MA.

Improvement with ZORYVE cream 0.15% was seen across multiple patient-reported outcomes including SCORing AD (SCORAD) total score[i], Patient-Oriented Eczema Measure (POEM), and Dermatitis Family Impact (DFI) compared to vehicle at 4 weeks, with improvement reported as early as Week 1, the first timepoint measured. These assessments score the improvement of physical symptoms such as redness and itchiness, as well as impact on loss of sleep, emotional distress, and daily activities (such as schoolwork, housework, or social activities).

“AD is a chronic, complex disease that can negatively affect the individual and the broader family unit, impacting relationships, sleep, and basic functions in life, like school attendance, housework, food preparation, and more,” said Mark Boguniewicz, MD, professor in the Division of Allergy-Immunology, Department of Pediatrics, at National Jewish Health and University of Colorado School of Medicine , and presenting author. “These new data show that treatment with ZORYVE not only provides rapid disease clearance and significant reduction in itch for the patient, but extends beyond that, reducing the impact of quality of life challenges that families and caregivers experience as a result of having a loved one living with a chronic skin disease like AD.”

Treatment with ZORYVE improved all patient-reported outcomes measured compared to vehicle including:

- 64.2% of individuals treated with ZORYVE cream achieved a clinically meaningful improvement in SCORAD Total Score compared to 36.3% treated with vehicle at Week 1 [i,ii] (P<0.0001).
- 46.2% of individuals treated with ZORYVE cream demonstrated improvement in SCORAD Total Score compared to 26.6% of patients treated with vehicle at Week 4 (P<0.0001).
- 61.7% of ZORYVE cream treated individuals achieved a clinically meaningful improvement in POEM scores compared to 34.2% treated with the vehicle at Week 1 (P<0.0001).
- Greater improvement in POEM scores were seen with ZORYVE cream compared to vehicle at Week 4 (7.5 vs. 3.9; P<0.0001).
- Greater improvement in DFI scores were seen with ZORYVE cream treated patients compared to vehicle at Week 4 (3.12 vs. 1.74; P<0.0001).

"When evaluating different treatment options for chronic skin conditions we often focus on the clinical efficacy outcomes, like disease clearance or reduction in symptoms like itch. However, this is just one piece of the puzzle and it’s just as important to understand the improvement in other aspects of patients’ lives that are impacted by this chronic disease,” said Patrick Burnett, MD, PhD, FAAD, chief medical officer of Arcutis. “We’re proud to share these data showcasing rapid improvement in patient reported outcomes, which translate to meaningful relief with ZORYVE cream for those with AD their families, and caregivers.”

As previously reported and published in *JAMA Dermatology*, across both studies (INTEGUMENT-1 and INTEGUMENT-2) ZORYVE cream 0.15% met the primary efficacy endpoint of Investigator Global Assessment (IGA) Success, defined as a validated Investigator Global Assessment – Atopic Dermatitis (vIGA-AD) score of *Clear* or *Almost Clear* plus a 2-grade improvement from baseline at Week 4 (31.3% ZORYVE cream vs. 14.1% vehicle, P<0.0001). ZORYVE cream 0.15% was safe and well tolerated. The Incidence of Treatment Emergent Adverse Events (TEAEs) was low in both ZORYVE- and vehicle-treated patients. The most common adverse reactions were headache, nausea, application site pain, diarrhea, and vomiting.

INTEGUMENT-1 and INTEGUMENT-2 (The INterventional Trial EvaluatinG roflUMilast cream for the treatmENt of aTopic dermatitis) were two identical Phase 3, parallel group, double blind, vehicle-controlled trials evaluating the safety and efficacy of ZORYVE cream 0.15% or vehicle applied once-daily for four weeks to 1,337 adults and children 6 years of age and older with mild to moderate AD.

Presentation Details
“Patient-reported Outcomes and Family Impact With Roflumilast Cream in Atopic Dermatitis: Pooled Phase 3 Results”
Session: Distinguished Industry & Late-breaking Oral Abstracts - Session 2

Room: 311311
Saturday, Oct. 26, 2024; 4:30 PM (ET) session; 5:13 PM (ET) presentation
Presenter: Mark Boguniewicz, MD

About Atopic Dermatitis
AD is the most common type of eczema, affecting approximately 9.6 million children and 16.5 million adults in the United States.

AD is a chronic, relapsing inflammatory skin disease that is genetically pre-disposed and presents across the lifespan. The disease may appear as a red, intensely itchy rash that can occur anywhere on the body and may present differently in children and adults. AD presentation can rapidly fluctuate and vary based on geographic location and environment.

About ZORYVE Cream
ZORYVE (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 atopic dermatitis, in patients 6 years of age and older. A lower dose, roflumilast cream 0.05%, was evaluated for children aged 2 to 5 years and based on the positive data Arcutis intends to submit a supplemental New Drug Application.

Indications
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.

IMPORTANT SAFETY INFORMATION
ZORYVE is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C).

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 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%).

Please see 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
Arcutis cautions you that 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 real-world use results of ZORYVE cream in AD, including patient reported outcomes, and the potential for ZORYVE cream to advance the standard of care in AD 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 27, 2024, as well as any subsequent filings with the SEC. You should not place undue reliance on any forward-looking statements in this press release. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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

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

[i] SCORAD (Scoring Atopic Dermatitis) combines investigator-assessed objective symptoms such as extent and intensity of redness, swelling and ozzing with patient reported subjective criteria such as itch and sleeplessness

[ii] As measured by Minimal Important Difference (MID), representing the point at which a difference in an outcome measure is important enough to warrant a change in treatment