New Data Shows ZORYVE® (Roflumilast) Cream 0.15% Provided Consistent Improvement of Atopic Dermatitis in Individuals With Diverse Skin Types

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- ZORYVE demonstrated consistent efficacy in disease clearance and reduction in itch for individuals with atopic dermatitis (AD) regardless of race, ethnicity, and Fitzpatrick skin type
- ZORYVE was safe and well tolerated across all subgroups
- Data presented at the 2024 European Academy of Dermatology & Venereology Congress

WESTLAKE VILLAGE, Calif., Sept. 24, 2024 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology and immunology, today announced new pooled subgroup analysis results from the Phase 3 INTEGUMENT-1 and -2 trials showing that ZORYVE cream 0.15% provided consistent and meaningful improvements in signs and symptoms of AD in individuals regardless of race, ethnicity, and Fitzpatrick skin types. The results will be presented in a poster at the European Academy of Dermatology & Venereology Congress held September 25-28, 2024, in Amsterdam.

At Week 4, higher percentages of Validated Investigator Global Assessment for AD (vIGA-AD) Success for ZORYVE- vs. vehicle-treated patients were observed regardless of race (White: 32.3% vs. 13.3%; Black or African American: 25.8% vs 11.5%; Asian: 33.7% vs. 21.8%; Others: 33.2% vs. 13.7%), ethnicity (Hispanic or Latino: 32.9% vs. 16.5%; Not Hispanic or Latino: 31.1% vs 13.8%), or Fitzpatrick score (I–III: 33.0% vs. 13.4%; IV–VI: 29.2% vs. 14.8%). The Fitzpatrick skin type is a scale of I to VI that classifies the skin by its reaction to exposure to sunlight, with skin type I being pale white skin that always burns, does not tan, to VI being dark brown or black skin that never burns, always tans darkly. vIGA-AD Success was defined as vIGA-AD value of 0 or 1 plus a 2-grade improvement from baseline.

“Given that the clinical presentation of AD may differ among patients by race, ethnicity, and Fitzpatrick skin type, it is reassuring to see the consistency of efficacy, safety, and tolerability of a treatment across these various subgroups,” said Vimal H. Prajapati MD, FRCPC, DABD, clinical associate professor at the University of Calgary and co-founder/co-director of the Skin Health & Wellness Centre, Dermphi Centre, Dermphi Shop, and Dermatology Research Institute. “ZORYVE cream 0.15% consistently achieved meaningful and significant improvements in disease clearance and itch reduction, in all subgroups. This analysis can give confidence to clinicians that ZORYVE provides effective and well-tolerated relief of atopic dermatitis signs and symptoms across individuals with diverse skin types.”

ZORYVE-treated patients also achieved a greater improvement in itch as measured by reductions in Worst Itch-Numeric Rating Scale (WI-NRS) Success, defined as ≥4-point improvement in patients 12 years of age and older with baseline WI-NRS score ≥4, at Week 4 with consistent results regardless of subgroup (White: 33.5% vs. 16.5%; Black or African American: 30.6% vs. 21.0%; Asian: 25.4% vs. 7.9%; Others: 34.3% vs. 22.7%), ethnicity (Hispanic or Latino: 37.4% vs. 30.5%; Not Hispanic or Latino: 30.9% vs. 13.8%), or Fitzpatrick score (I–III: 35.5% vs. 15.0%; IV–VI: 27.3% vs. 18.2%). Similar findings were observed for additional endpoints including achievement of vIGA-AD score of ‘Clear (0)’ or ‘Almost Clear (1)’ and 75% improvement in the Eczema Area and Severity Index (EASI-75).

"We formulated ZORYVE cream with all AD patients in mind, and we are pleased to present these data from our Phase 3 INTEGUMENT studies, which demonstrated ZORYVE’s ability to significantly, consistently, and safely improve AD symptoms regardless of race, ethnicity, or skin type,” said Patrick Burnett, MD, PhD, FAAD, chief medical officer of Arcutis. “It is critical that our clinical data represent the diversity in the world around us, and these results further reinforce our commitment to providing meaningful innovation for immune-mediated skin diseases.”

The Incidence of Treatment Emergent Adverse Events (TEAEs) was low in both ZORYVE- and vehicle-treated patients. The incidence of TEAEs in ZORYVE-treated patients was generally similar across subgroups. Local tolerability was also favorable. 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% in AD.

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 appears 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 the Company 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 that clinical trial results will translate to real-world use of ZORYVE cream in AD including individuals with diverse skin types, 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