Arcutis to Present New Long-Term Results of ZORYVE® (roflumilast) Cream at the 2025 Revolutionizing Atopic Dermatitis Conference

June 6, 2025

- New data from the Phase 3 INTEGUMENT-OLE long-term open label study show durable improvement in the signs and symptoms of atopic dermatitis (AD), including almost half of participants achieving no or minimal itch with ZORYVE cream 0.15% or ZORYVE cream 0.05%
- New data demonstrate that for children ages 2 to 5 who achieved disease clearance and switched to proactive twice-weekly application of investigational ZORYVE cream 0.05%, the median duration of disease control was 238 days
- Consistent efficacy, safety, and tolerability profile observed with ZORYVE cream

WESTLAKE VILLAGE, Calif., June 06, 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 five posters at the 2025 Revolutionizing Atopic Dermatitis (RAD) Conference**,** which is taking place in Nashville, TN, from June 6-7, 2025.

Importantly, the Company will present new data from its INTEGUMENT-OLE study demonstrating the long-term safety and durable efficacy of investigational ZORYVE cream 0.05% in children ages 2 to 5 with AD, consistent with previous studies. Starting at Week 4 of INTEGUMENT-OLE, participants who achieved a validated Investigator Global Assessment (vIGA-AD) score of clear (0), switched to proactive twice-weekly application (170 participants; 30.2% of study population). For participants who switched to twice-weekly application, the median duration of disease control (maintaining vIGA-AD of clear or almost clear with adequate control of signs and symptoms on the twice-weekly schedule application) was 238 days (34 weeks), consistent with the 281 days observed for adults and children down to age 6 who used twice-weekly dosing.

Additional poster presentations will present data demonstrating that in individuals 2 years of age and older with AD, ZORYVE cream 0.15% or investigational ZORYVE cream 0.05% decreased signs and symptoms of AD — including a clinically meaningful improvement in itch as well as reduction in mean percent body surface area (BSA) affected over time — and these improvements were maintained or improved further with long-term treatment, including in those who switched to twice-weekly application. Specifically, at the end of the parent studies (Week 4), 32.7% of participants 6 years and over, and 28.8% of participants 2 to 5 years achieved vIGA-AD 0/1, which improved to 55.7% and 63.1%, respectively, by the end of the INTEGUMENT-OLE study (Week 52), amounting to up to 56 weeks of treatment. In addition, itch was improved, with 30.9% of participants 6 years and over and 41.2% of participants 2 to 5 years achieving clinically meaningful reduction in Worst Itch Numeric Rating Scale (WI-NRS) (≥4-point reduction) at the conclusion of the parent studies, improving to 55.3% and 60.7%, respectively, after up to 56 weeks of treatment. Substantial proportions of participants also achieved no or minimal itch by end of treatment (47.1% of those aged ≥6 years and 40.7% of those aged 2–5 years as measured by WI-NRS of 0 or 1).

“Chronic use of topical steroids in patients with AD, especially in young children, is associated with significant adverse events, making steroid-free options critical in this population. There is a significant need for effective, long-term treatments among patients of all ages, but especially young children whose AD symptoms can often become so overwhelming that the condition impacts the entire family,” said Jonathan Silverberg, MD, PhD, MPH, a professor of dermatology and the director of clinical research and contact dermatitis at The George Washington University School of Medicine and Health Sciences in Washington, DC. “These data highlight that ZORYVE cream 0.15% and investigational ZORYVE cream 0.05% provided long-term improvements in AD signs and symptoms, including reductions in itch and BSA, in children and adults who transitioned from once-daily to a twice-weekly application. These findings reinforce the well-established efficacy and safety profile we’ve seen with the ZORYVE cream 0.15% formulation and build further confidence in the potential of investigational ZORYVE cream 0.05% formulation, especially as a long-term, steroid-free option for younger children where tolerability and safety are paramount.”

ZORYVE cream 0.15% and investigational 0.05% were well tolerated. Treatment-related Adverse Events in INTEGUMENT-OLE were reported for 4.7% in participants 6 years and over and 2.5% of participants 2 to 5 years. Application-site pain was reported as an adverse event for 0.5% of participants 6 years and older and 0.7% of participants 2 to 5 years.

“AD presents unique challenges in this youngest age group, not only because the skin is more sensitive, but also because the condition often covers a greater percentage of their total body surface area compared to older children and adults. In addition, long-term management of AD requires treatment that can deliver rapid relief of itch, sustained symptom improvement over time, and that is tolerable when applied to the skin,” said Patrick Burnett, MD, PhD, FAAD, chief medical officer at Arcutis. “Our goal is to address this unmet need by providing advanced targeted topical therapies that can manage symptoms effectively over the long-term, while also improving the quality of life for individuals and their families living with this chronic condition."

Poster Presentations
The following posters will be available electronically at the conference beginning Friday, June 6, 2025, and will be available for the duration of the conference:

Improvement in Atopic Dermatitis Signs and Symptoms with Once-Daily and Proactive Twice-Weekly Roflumilast Cream 0.15% or 0.05%: Results from the 52-Week Phase 3 INTEGUMENT-OLE Trial in Patients Aged ≥2 Years
Hong, H C-ho et al.

Long-term Safety and Maintenance of Efficacy with Once-Daily/Proactive Twice-Weekly Roflumilast Cream 0.05% in 2–5-year-olds with Atopic Dermatitis: Data from a 52-Week, Phase 3 Trial (INTEGUMENT-OLE)
Eichenfield, L et al.

INTEGUMENT-INFANT: A Phase 2, 4-Week, Open-Label Safety Study of Roflumilast Cream 0.05% in Infants Aged 3 Months to Less Than 2 Years with Atopic Dermatitis
Hebert, A et al.

Efficacy and Tolerability of Roflumilast Cream 0.15% for Atopic Dermatitis: Pooled Subgroup Analysis of Patients with Face/Eyelid Involvement from Phase 3 INTEGUMENT-1/2 Trials
Simpson, E et al.

Pooled Safety and Application-Site 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.

About INTEGUMENT-OLE
The "INterventional Trial Evaluating roflUMilast cream for the treatmENt of aTopic dermatitis" Open Label Extension (INTEGUMENT-OLE) was a Phase 3, multicenter, open-label extension study of the long-term safety of roflumilast cream 0.15% in adults and children ages 6 years and older with AD and roflumilast cream 0.05% in children ages 2 to 5 years with AD. A total of 658 children and adults from INTEGUMENT-1 and -2 and 562 children from INTEGUMENT-PED enrolled in the INTEGUMENT-OLE study.

The study evaluated monotherapy with ZORYVE cream 0.15% or ZORYVE cream 0.05%, with no rescue treatment permitted. Beginning at Week 4 of INTEGUMENT-OLE, any participant who achieved vIGA-AD of '0-Clear' switched to twice-weekly maintenance treatment. Participants were able to continue twice-weekly maintenance dosing as long as vIGA-AD remained either '0 -Clear' or '1-Almost Clear'. Participants resumed once-daily dosing if vIGA-AD reached ≥2-Mild, or could also resume once-daily dosing if signs/symptoms of AD were not adequately controlled with maintenance therapy.

About ZORYVE (roflumilast)
ZORYVE is the first and only branded topical therapy for three major inflammatory dermatoses: atopic dermatitis, seborrheic dermatitis, and plaque psoriasis. ZORYVE 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. ZORYVE (roflumilast) cream 0.3% is approved by the 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 atopic dermatitis 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) topical foam 0.3% is uniquely formulated for use anywhere on the body, including hair-bearing areas, and is indicated for treatment of plaque psoriasis of the scalp and body in patients 12 years of age and older, as well as seborrheic dermatitis in patients 9 years of age and older. Recently, both ZORYVE cream 0.3% and ZORYVE foam 0.3% were awarded the National Psoriasis Foundation's Seal of Recognition —the first FDA-approved product to receive the honor.
Investigational ZORYVE (roflumilast) cream 0.05% for the topical treatment of mild to moderate AD in children 2 to 5 years old is under review by the FDA with a Prescription Drug User Fee Act (PDUFA) target action date of October 13, 2025.

INDICATIONS
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.

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.

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 foam 0.3% for plaque psoriasis include headache (3.1%), diarrhea (2.5%), nausea (1.7%), and nasopharyngitis (1.3%).

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%).

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 of advanced targeted topicals approved to treat three major inflammatory skin diseases. Arcutis' unique dermatology development platform coupled with our dermatology expertise allows us to invent differentiated therapies against biologically validated targets and has produced a robust pipeline with multiple follow-on clinical programs for a range of inflammatory dermatological conditions including atopic dermatitis 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 FDA approval of ZORYVE cream 0.05%, the potential that the clinical trial results of long-term use of ZORYVE cream 0.15% and ZORYVE cream 0.05% will translate into real world results, and the potential for ZORYVE cream 0.15% and ZORYVE cream 0.05% to advance the standard of care in AD. 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, 2025, 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.

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