Arcutis to Present New Quality of Life and Long-Term Data with ZORYVE® (roflumilast) Cream 0.15% and 0.05% for the Treatment of Atopic Dermatitis at the Fall Clinical Dermatology Conference

October 24, 2025

- New data from Phase 3 studies show once-daily ZORYVE cream helped reduce sleep disruptions in individuals with atopic dermatitis aged ≥2 years
- New long-term data demonstrate that ZORYVE cream was well-tolerated and provided continued disease control for individuals who switched to twice-weekly treatment

WESTLAKE VILLAGE, Calif. and LAS VEGAS, Oct. 24, 2025 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced that new data demonstrating ZORYVE® (roflumilast) cream 0.15% and 0.05% improved quality of life, specifically by helping to reduce sleep disruptions, and provided long-term, durable disease control for individuals with atopic dermatitis aged 2 years and older will be presented at the 2025 Fall Clinical Dermatology Conference, taking place October 23–26, 2025, in Las Vegas.

“We continue to build upon the body of evidence for ZORYVE cream in atopic dermatitis with these presentations at Fall Clinical, including one of the first analyses to report on improvements in sleep as measured through patient reported outcome data. A separate poster presentation demonstrated that ZORYVE cream decreased signs and symptoms of atopic dermatitis in children aged 2 years and older. Importantly, a decrease in the body surface area affected was maintained or improved over 52 weeks of treatment with ZORYVE cream, which is meaningful improvement in children who often have more widespread disease across their smaller bodies,” said Patrick Burnett, MD, PhD, FAAD, chief medical officer, Arcutis Biotherapeutics. “These findings reinforce ZORYVE as an advanced targeted topical treatment and a meaningful alternative to topical corticosteroids—providing effective, well-tolerated therapy for individuals living with atopic dermatitis in need of long-term disease control.”

Roflumilast Cream 0.15% and 0.05% Effects on Sleep in Patients with Atopic Dermatitis
M. Gonzalez, et al.
New patient- and caregiver-reported outcomes on the impact of once-daily ZORYVE cream across three Phase 3, randomized, controlled trials demonstrate that ZORYVE cream 0.15% and 0.05% improved itch and reduced the negative impact of atopic dermatitis on sleep in individuals aged ≥6 years and 2–5 years, respectively, throughout four weeks of treatment compared to vehicle (INTEGUMENT-1/INTEGUMENT-2 aged ≥6 years; n=884 treated with ZORYVE cream 0.15%; n=453 treated with vehicle cream; INTEGUMENT-PED aged 2–5 years; caregiver-applied; n=436 treated with ZORYVE cream 0.05%; n=215 treated with vehicle cream).

Specific results include:

- ZORYVE cream reduced the impact of atopic dermatitis on sleep loss/disturbance for study participants and families as compared to vehicle across multiple patient-reported outcome measurements.[1] In addition, the reduced impact of atopic dermatitis on sleep for individuals with atopic dermatitis (and their family, in patients aged ≤17 years) was similar among the ≥6-year and 2–5-year-old age groups.
- As previously reported, ZORYVE cream was also shown to reduce itch as measured by the daily Worst Itch Numeric Rating Scale (WI-NRS).[2] Improvements from baseline were greater with ZORYVE cream versus vehicle throughout the trials including at Week 4 (INTEGUMENT-1/2: 2.6 vs 1.6; P<0.001; INTEGUMENT-PED: 2.6 vs 1.6; P<0.01). On average, there was a greater reduction in mean WI-NRS scores within 24 hours of the first application among patients treated with ZORYVE compared to patients treated with vehicle (P<0.005) in both INTEGUMENT-1/2 and INTEGUMENT-PED.
- ZORYVE was well tolerated, with treatment-related adverse events (AEs) and serious AEs reported by ≤6% and <1% of patients, respectively, in the ZORYVE group, from any of the studies. Application-site pain AEs were reported for 13 (1.5%) of individuals in the ZORYVE group in INTEGUMENT-1/2 and 7 (1.6%) of individuals in INTEGUMENT-PED.

“Sleep disruption is a persistent and often overlooked but very real daily burden for those impacted by atopic dermatitis, including young children and their families,” said Mercedes E. Gonzalez, MD, medical director of Pediatric Skin Research, LLC, INTEGUMENT-PED clinical trial investigator, and lead author of the poster. “ZORYVE offers a safe, nonsteroidal, and targeted treatment option. In addition, these results highlight the clinically meaningful benefit of ZORYVE cream on reducing itch and improving sleep in young children with atopic dermatitis.”

Once-Daily Roflumilast Cream 0.15% and 0.05% Improve Atopic Dermatitis Signs and Symptoms that Can be Maintained with Proactive Twice-Weekly Treatment: Results From the 52-Week Phase 3 INTEGUMENT-OLE Trial in Patients Aged ≥2 Years
A. Herbert et al.
New long-term data from INTEGUMENT-OLE, a 52-week, Phase 3, multicenter, open-label extension (OLE) trial in individuals aged ≥2 years with mild-to-moderate atopic dermatitis show that ZORYVE cream 0.15% and 0.05% were well tolerated, decreased signs and symptoms of atopic dermatitis, and maintained or increased improvements through up to 56 weeks of treatment in individuals aged ≥2 years. Study participants previously completed one of the pivotal Phase 3 trials, INTEGUMENT-1 or INTEGUMENT-2 (n=658) or INTEGUMENT-PED (n=562).

Key results include:

- As previously reported, the data demonstrate that, even in young children 2-5 years of age who have a higher body surface area (BSA) affected, the decrease in mean BSA affected through 4 weeks of treatment with ZORYVE cream in pivotal Phase 3 trials was maintained and improved further over an additional 52 weeks of treatment in the OLE study (INTEGUMENT-1/2: 14.8% to 3.7%; INTEGUMENT-PED: 22.3% to 4.9%).
- Starting at Week 4 of INTEGUMENT-OLE, participants who achieved a vIGA-AD[3] score of 'Clear' (0), switched to proactive twice-weekly application (ZORYVE cream 0.05% n=170; 30.2% of 562 children ages 2-5; ZORYVE cream 0.15% n=130; 19.8% of 658 adults and children ≥6). 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 in children 2-5 and 281 days in adults and children 6 years of age and older.
- As previously reported, ZORYVE cream maintained efficacy over time and demonstrated continued improvements in clearance as measured by vIGA-AD and itch as measured by WI-NRS.
    - At 56 weeks, the percent of patients achieving vIGA-AD 'Clear' or 'Almost Clear' (0/1) were 55.7% (117 of 210) in the INTEGUMENT-1/2 populations and 63.1% (234 of 371) in the INTEGUMENT-PED population, compared to 41.3% and 40.3% at Week 4 of the OLE study, respectively.
    - At 56 weeks, the percent of patients achieving WI-NRS rating of no/minimal itch (0/1) with ZORYVE cream were 41.4% (53 of 128) in the INTEGUMENT-1/2 population and 40.7% (116 of 285) in the INTEGUMENT-PED population, compared to 25.5% and 25.5% at Week 4 of the OLE study, respectively.
    - The rate of treatment related adverse events (AEs) during the OLE study was 2.5% in the INTEGUMENT-PED population and 4.7% in the INTEGUMENT-1/2 population, and application-site pain AEs <1% across both populations.

About ZORYVE® (roflumilast)
ZORYVE is the number one prescribed branded topical therapy across three major inflammatory dermatoses combined—atopic dermatitis, seborrheic dermatitis, and plaque psoriasis. ZORYVE cream is a topical formulation of roflumilast, an advanced targeted topical phosphodiesterase type 4 (PDE4) inhibitor. Inhibiting PDE4, an intracellular enzyme that is an established target in dermatology, decreases the production of pro-inflammatory mediators. This decreases inflammation in the skin and balances the skin's immune system.

Demonstrating both clinical impact and broad industry recognition, ZORYVE has been honored with multiple prestigious awards and recommendations. ZORYVE was recently awarded by *Allure* with the "2025 Best of Beauty Breakthrough Award," making it the first FDA-approved medication for atopic dermatitis, plaque psoriasis, and seborrheic dermatitis to win this prominent award. ZORYVE cream 0.3% and ZORYVE foam 0.3% were also awarded the National Psoriasis Foundation's Seal of Recognition — the first FDA-approved prescription brand to receive the honor. Additionally, the American Academy of Dermatology (AAD) issued a strong recommendation for the use of ZORYVE cream 0.15% in adult patients with mild to moderate atopic dermatitis, according to updated guidelines released in June 2025. In 2024, ZORYVE cream 0.15% was awarded *Glamour's* Beauty and Wellness Award for "Best Eczema Product."

INDICATIONS
ZORYVE cream, 0.05%, is indicated for topical treatment of mild to moderate atopic dermatitis in pediatric patients 2 to 5 years of age.

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).

The most common adverse reactions reported (≥1%) for ZORYVE cream 0.05% for pediatric patients with atopic dermatitis 2 to 5 years of age were upper respiratory tract infection (4.1%), diarrhea (2.5%), vomiting (2.1%), rhinitis (1.6%), conjunctivitis (1.4%), and headache (1.1%).

The most common adverse reactions reported (≥1%) for ZORYVE cream 0.15% for patients with atopic dermatitis 6 years of age or older were 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 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 develop differentiated therapies against biologically validated targets and has produced a robust pipeline for a range of inflammatory dermatological conditions. 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 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 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.

[1]Sleep-related PROs were determined for the following assessments: SCORAD (sleep loss over the past 3 days/nights; scores ranging from 0 (none) to 10 (most severe) are reported as LSM improvement from baseline); POEM (sleep disturbance over the past week for 0 days, 1–2 days, 3–4 days, 5–6 days, or every day); CDLQI (patients aged 4–16 years; sleep affected in the past week rated as not at all, a little, a lot, or very much); IDQoL ((INTEGUMENT-PED only, patients aged <4 years) Total time of sleep disturbance in the past week rated as <1 hour, 1–2 hours, 3–4 hours, or ≥5 hours, Average time to get a child to fall asleep each night in the past week rated as 0–15 minutes, 15 minutes to 1 hour, 1–2 hours, or >2 hours); DFI (parent/caregiver of patients aged ≤17 years; sleep disturbance and tiredness/exhaustion of family members)

[2]Itch levels were tracked and reported by caregivers of children daily. Scores range from 0 (no itch) to 10 (worst itch imaginable. This technique may need more testing to confirm its accuracy in children under 12 years old. Results may vary.

[3]vIGA-AD (Validated Investigator Global Assessment Atopic Dermatitis) is a 5-point scale to assess the overall severity of atopic dermatitis, with 0 meaning clear and 4 meaning severe.

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