



Arcutis Presents ZORYVE® (roflumilast) Data and Real-World Topical Corticosteroid Research at EADV and Fall Clinical

October 9, 2026

- Presentation of data from the INTEGUMENT-INFANT trial of investigational ZORYVE cream 0.05% in infants ages 3 to <24 months, where treatment options remain limited
- New analyses from the ARRECTOR and DERMIS-1/2 trials further demonstrate ZORYVE's efficacy and symptom improvements across the body in individuals with psoriasis
- Additional data from collaborative research reinforce the inflammatory pathway and barrier impairment involved in seborrheic dermatitis
- Real-world research examines the role long-term topical corticosteroid use plays in the care of adults and children with chronic inflammatory skin conditions

WESTLAKE VILLAGE, Calif., Oct. 09, 2026 (GLOBE NEWSWIRE) -- [Arcutis Biotherapeutics, Inc.](#) (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced data presented across its ZORYVE® (roflumilast) portfolio as well as real-world research on the long-term use of topical corticosteroids at the 35th European Academy of Dermatology and Venereology (EADV) Congress, held Sept. 30-Oct. 3 in Vienna, Austria, and the Fall Clinical Dermatology Conference, held Oct. 8-11 in Las Vegas, Nevada.

"The data presented at these two meetings add to the growing body of evidence supporting ZORYVE across three chronic inflammatory skin conditions and a wide range of ages, including infants, the most vulnerable and underserved patient populations. The results include positive data for once-daily ZORYVE cream in infants ages 3 to 24 months with atopic dermatitis, and ZORYVE cream and foam in people with psoriasis, including genital involvement and the impact of disease on sexual function and personal relationships," said Frank Watanabe, president and chief executive officer of Arcutis. "We also shared new collaborative research on the pathophysiology of seborrheic dermatitis that further characterizes the cutaneous molecular signature of the disease."

ZORYVE (roflumilast) data and research advancing disease insights:

Arcutis presented data from the Phase 2 INTEGUMENT-INFANT study of investigational once-daily ZORYVE cream 0.05% in infants aged 3 to less than 24 months with atopic dermatitis. ZORYVE cream 0.05% is approved for topical treatment of mild to moderate atopic dermatitis in children aged 2 to 5 years, and is under review by the U.S. Food and Drug Administration (FDA) for the treatment of infants 3 to less than 24 months old with a Prescription Drug User Fee Act (PDUFA) target action date of February 23, 2027. The company also presented two analyses of ZORYVE foam 0.3% and ZORYVE cream 0.3% in the treatment of plaque psoriasis in special sites, including the scalp and genitals, drawn from the Phase 3 ARRECTOR and DERMIS-1/2 trials. In addition, collaborators at Mount Sinai presented new findings underscoring the inflammatory pathway of seborrheic dermatitis, its unique cutaneous molecular signature, and barrier impairment via proteomics measured on both tape strips and skin biopsies.

- **INTEGUMENT-INFANT: Once-Daily Roflumilast Cream 0.05% in Infants Aged 3 to <24 Months With Atopic Dermatitis.**

L. Eichenfield, et al.

EADV Congress, Poster P2401.

In this Phase 2 study, investigational once-daily ZORYVE cream 0.05% was well tolerated in 101 infants with atopic dermatitis, with no serious adverse events and no evidence of application-site irritation for at least 97.9% of infants. ZORYVE cream 0.05% demonstrated rapid disease clearance through 4 weeks of treatment. Among infants who completed 4 weeks of treatment in INTEGUMENT-INFANT (n=96), 34.4% achieved Validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD) Success, defined as a score of 0 (Clear) or 1 (Almost Clear) with a ≥2-grade improvement from baseline. Additionally, IGA-Scalp Success, defined as a score of 0 (Clear) or 1 (Almost Clear) with a ≥2-grade improvement from baseline, was achieved by 67.5% of infants. Caregivers also reported rapid itch improvement, with 46.6% of infants achieving at least a 25% improvement in pruritus (itch) from baseline within 10 minutes of application, as assessed by caregivers, based on the Dynamic Pruritus Scale (DPS-25) (n=88).

- **Pattern of Improvement in Scalp Versus Body Psoriasis With Roflumilast Foam 0.3%: An Analysis of the Phase 3 ARRECTOR Trial.**

M. Gooderham, et al.

Fall Clinical Dermatology Conference.

In a subanalysis of the Phase 3 trial of 432 patients aged 12 and older, more patients treated with ZORYVE foam 0.3% than vehicle foam achieved clear or almost clear skin at Week 8 on both the scalp (66.4% vs 27.8%) and the body (45.5% vs 20.1%). Within 24 hours of the first application, individuals treated with ZORYVE experienced greater improvement in mean itch scores compared to vehicle (SI-NRS, defined as a patient-reported measure of scalp itch severity: Least-squares mean improvement of 0.44 vs 0.09; WI-NRS, defined as a patient-reported measure of worst itch severity: Least-squares

mean improvement of 0.42 vs 0.01).

- **Improvements in Psoriasis, Including Sexual Function and Personal Relationships, With Roflumilast Cream 0.3% and Foam 0.3%: Outcomes From the Phase 3 DERMIS-1/2 and ARRECTOR Trials.**

M. Payette, et al.

Fall Clinical Dermatology Conference.

This analysis of patients from the DERMIS-1/2 and ARRECTOR studies found that ZORYVE cream 0.3% and foam 0.3% improved psoriasis signs and symptoms and quality of life, along with patient-reported sexual function and personal relationships, through Week 8, in individuals with psoriasis both with and without genital involvement at baseline.

- **Tape-strip Proteomic Profiling and Biopsy Validation Highlight Inflammatory Pathogenesis in Seborrheic Dermatitis.**

E. Guttman, et al.

EADV Congress, Poster P2290.

Using proteomic analysis of tape strips and skin biopsies from adults with seborrheic dermatitis, this collaborative research identified the inflammatory pathways driving the disease and the skin barrier impairment that distinguishes it from atopic dermatitis, while also highlighting seborrheic dermatitis as a primarily Th17-mediated disease.

Real-world topical corticosteroid research:

Arcutis will present for the first time real-world survey research developed in collaboration with the National Eczema Association and the National Psoriasis Foundation, alongside a new targeted review of published literature on adverse events associated with topical corticosteroid use.

- **Real-World Topical Corticosteroid Treatment Patterns and Perceptions of Disease Control Among Adults and Caregivers of Children With Atopic Dermatitis, Psoriasis, or Seborrheic Dermatitis.**

E. Simpson, et al.

Fall Clinical Dermatology Conference.

In a survey of 1,000 adults and 500 caregivers of children prescribed topical corticosteroids for plaque psoriasis, atopic dermatitis, and seborrheic dermatitis, most agreed their treatment focused on reacting to flares rather than long-term control (78.8% of adults, 77.6% of caregivers). About a third experienced uncontrolled symptoms at least weekly (36.1% adults; 32.8% children). Furthermore, even when symptoms were controlled, more than half of adults (56.7%) and caregivers (54.8%) reported anxiety over symptoms becoming uncontrolled, which was greater for patients prescribed more than one corticosteroid.

- **Real-World Long-Term Topical Corticosteroid Use and Adverse Event Concerns Among Adults and Caregivers of Children With Atopic Dermatitis, Psoriasis, or Seborrheic Dermatitis.**

T. Bhutani, et al.

Fall Clinical Dermatology Conference.

A companion analysis of the same survey described above found that many respondents did not use topical corticosteroids as prescribed, often citing concerns about skin thinning and long-term side effects. Nearly half hesitated to raise concerns about long-term steroid use with their provider (47.8% of adults, 45.0% of caregivers). Furthermore, corticosteroid hesitancy was significantly associated with prior treatment experience: Hesitancy was higher among individuals who had ever experienced a negative reaction to a corticosteroid vs. those who had not (adults: 61.6% vs 34.7%; children: 57.0% vs 34.6%) and among those prescribed more than one corticosteroid vs. one corticosteroid (adults: 56.1% vs 43.8%; children: 53.9% vs 38.2%).

- **Cutaneous and Systemic Adverse Events Associated With Topical Corticosteroid Use: A Targeted Literature Review.**

A. Golant, et al.

EADV Congress, Poster P2706.

This review of literature published between August 2015 and September 2025 identified 42 case reports and series describing cutaneous and systemic adverse events in 83 patients treated with topical corticosteroids. Skin effects such as atrophy and striae appeared in 69.0% of publications, and the most common systemic side effects were Cushing's syndrome or features (47.6%) and HPA axis suppression/adrenal insufficiency (40.5%). The authors point to a need for improved prescribing practices, ongoing monitoring of adverse events and documentation of cumulative steroid exposure, highlighting a role for alternative therapies that control chronic disease without the limitations of steroids.

"This growing body of research deepens our understanding of what long-term topical corticosteroid use means for people living with chronic inflammatory skin conditions," said Patrick Burnett, MD, PhD, FAAD, chief medical officer of Arcutis. "This includes findings from a real-world survey, presented at a medical congress for the first time, alongside a targeted review of the literature examining adverse events associated with topical corticosteroid use. Together, these data provide important context on treatment patterns, perceptions of disease control, and patient and caregiver concerns around long-term use, helping to inform continued discussions around responsible and appropriate topical corticosteroid use and steroid stewardship in the management of chronic inflammatory skin diseases."

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 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, including three from major beauty magazines:

- *Allure's* "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;
- *Glamour's* 2024 Beauty and Wellness Award for "Best Eczema Product," recognizing ZORYVE cream 0.15%;
- And most recently, *Marie Claire's* "2026 Best Prescription Skin Solution" Award, recognizing ZORYVE cream 0.15% for eczema.

In addition, ZORYVE has been honored with the following recommendations:

- National Psoriasis Foundation's Seal of Recognition for ZORYVE cream 0.3% and ZORYVE foam 0.3% — the first FDA-approved prescription brand to receive the honor.
- American Academy of Dermatology (AAD) issued a strong recommendation for the use of ZORYVE cream 0.15% in adults with mild to moderate atopic dermatitis, in updated guidelines released June 2025, as well as a strong recommendation for the use of ZORYVE cream 0.05% for children aged 2-5 years and ZORYVE cream 0.15% for children aged 6 years and older with mild to moderate atopic dermatitis from the AAD's first-ever pediatric atopic dermatitis guidelines published in April 2026.

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.

ZORYVE cream, 0.3%, is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in adult and pediatric patients 2 years of age and older.

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.

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 reported ($\geq 1\%$) 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 ($\geq 1\%$) 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%).

The most common adverse reactions reported ($\geq 1\%$) for ZORYVE cream 0.3% for plaque psoriasis were 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 reported ($\geq 1\%$) for ZORYVE foam 0.3% for plaque psoriasis were headache (3.1%), diarrhea (2.5%), nausea (1.7%), and nasopharyngitis (1.3%).

The most common adverse reactions reported ($\geq 1\%$) for ZORYVE foam 0.3% for seborrheic dermatitis were nasopharyngitis (1.5%), nausea (1.3%), and headache (1.1%).

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 delivering meaningful innovation to address the needs of individuals living with chronic inflammatory skin diseases. Over the past decade, Arcutis has successfully developed a robust portfolio of advanced targeted topicals approved to treat three major inflammatory skin diseases, driven by a commitment to solving the most persistent patient challenges in dermatology. Arcutis' unique dermatology development platform, built on established scientific pathways and coupled with deep clinical dermatology and commercial expertise, enables us to efficiently develop, scale, and deliver our differentiated therapies while advancing a growing pipeline across 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 potential FDA approval of ZORYVE cream 0.05% in infants 3 to 24 months, clinical trial and research results translating into real world results, and the potential for ZORYVE cream and ZORYVE foam to advance the standard of care in atopic dermatitis, plaque psoriasis, and seborrheic dermatitis. 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, 2026, 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

Brian Schoelkopf, Head of Investor Relations

ir@arcutis.com