Arcutis Launches ZORYVE® (roflumilast) Cream 0.05% for the Treatment of Mild to Moderate Atopic Dermatitis in Children Ages 2 to 5

October 30, 2025

- Once-daily, effective, safe, and well-tolerated ZORYVE cream 0.05% now commercially available for children as young as age 2
- ZORYVE cream 0.05% provides rapid clearance of atopic dermatitis
- ZORYVE can be used anywhere on the body for any duration and is not a steroid
- Atopic dermatitis is the most common type of eczema, affecting approximately 9.6 million children in the U.S.

WESTLAKE VILLAGE, Calif., Oct. 30, 2025 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced the commercial launch of ZORYVE® (roflumilast) cream 0.05% for the treatment of mild to moderate atopic dermatitis in children ages 2 to 5 years in the United States.

ZORYVE cream 0.05% is a once-daily, steroid-free topical treatment that provides long-term disease control with no limitation on duration of use. In clinical trials, ZORYVE cream 0.05% had positive results across all efficacy endpoints, including significant clearance of atopic dermatitis signs and symptoms and meaningful improvement in itch. This launch expands the ZORYVE portfolio to a younger pediatric population, making ZORYVE cream available for children with mild to moderate atopic dermatitis as young as 2 years old.

“Atopic dermatitis is one of the most common chronic skin conditions in young children, yet safe and effective long-term treatment options have been limited, especially for children ages 2 to 5,” said Todd Edwards, chief commercial officer at Arcutis. “With ZORYVE cream 0.05%, families have a once-daily, steroid-free, and well-tolerated treatment that targets the underlying inflammation of atopic dermatitis. ZORYVE provides a foundation for ongoing control, and can be used for any duration, anywhere on the body, with no restrictions on body surface area. We are excited to make this important treatment widely available to help improve outcomes for children and their families.”

ZORYVE cream 0.05% will be available in pharmacies this week. The product is being reviewed by commercial pharmacy benefit managers and other plans to enable similar coverage as the entire ZORYVE portfolio.

“In my practice, I’ve seen firsthand how challenging atopic dermatitis can be for young children who deal with discomfort from the itch and rash, which can disrupt daily activities and sleep at night. In addition, parents and caregivers are looking for treatments that are not a steroid and are easy to apply,” said Latanya Benjamin, MD, associate professor of pediatric dermatology at Florida Atlantic University’s Charles E. Schmidt College of Medicine. “I look forward to being able to offer ZORYVE cream 0.05% as a new advanced targeted topical for children with mild to moderate atopic dermatitis 2 to 5 years old and hopefully, bring some much-needed relief through its effective, yet gentle, skin-barrier-friendly formulation.”

Arcutis is dedicated to ensuring predictable access for the ZORYVE portfolio of products, with one simple copay card and fulfillment process. The ZORYVE® Direct Program helps patients access their prescribed Arcutis medication. Specifically, this patient support program helps those who have been prescribed ZORYVE to navigate the payer process, assists patients with adherence, and includes the ZORYVE Direct Savings Card Program, which can help reduce out-of-pocket costs for eligible commercially insured patients.† Arcutis will also continue to offer the Arcutis Cares™ patient assistance program (PAP) that provides ZORYVE at no cost for financially eligible patients who are uninsured or underinsured.‡

On October 6, 2025, Arcutis announced that the U.S. Food and Drug Administration (FDA) had approved ZORYVE cream 0.05% for the treatment of mild to moderate atopic dermatitis in children ages 2 to 5 years. For more information about ZORYVE, including full prescribing information, visit zoryve.com.

A Media Snippet accompanying this announcement is available by clicking on this link.

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.”

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.

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.

ZORYVE is for topical use only and not for ophthalmic, oral, or intravaginal use.

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 for ZORYVE cream to advance the standard of care in atopic dermatitis, including patients ages 2 to 5 years. 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.

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† Subject to eligibility criteria and maximum program limitation. This offer is not valid for patients without commercial drug insurance or whose prescription claims are eligible to be reimbursed, in whole or in part, by any government program.

‡ Subject to financial eligibility requirements. Other terms and restrictions apply.