FDA Approves Arcutis' ZORYVE® (roflumilast) Cream 0.05% for the Treatment of Atopic Dermatitis in Children Ages 2 to 5

October 6, 2025

- ZORYVE cream 0.05% provides rapid and effective relief of mild to moderate atopic dermatitis in children ages 2 to 5 and is safe and well tolerated
- Once-daily, steroid-free cream can be used anywhere on the body for any duration
- About 1.8 million children ages 2 to 5 with atopic dermatitis are topically treated in the U.S.
- Sixth FDA approval for ZORYVE in just over three years
- Commercial product expected to be available by the end of October 2025

WESTLAKE VILLAGE, Calif., Oct. 06, 2025 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company dedicated to developing meaningful innovations in immuno-dermatology, today announced that the U.S. Food and Drug Administration (FDA) has approved the supplemental new drug application (sNDA) for ZORYVE® (roflumilast) cream 0.05% for the topical treatment of mild to moderate atopic dermatitis in children 2 to 5 years of age. Once-daily ZORYVE cream 0.05% provides rapid and significant clearance of atopic dermatitis anywhere on the body and offers clinicians, parents, and caregivers of children ages 2 to 5 an alternative to steroids that can be used for any duration.

"It is essential to have safe and effective treatments for children, who are often diagnosed with atopic dermatitis at a young age and can live with the condition across their lifetime. Young children often experience widespread disease, affecting large portions of their skin. Although topical steroids have been the standard treatment for years, they are not appropriate for long-term use," said Lawrence F. Eichenfield, MD, chief of pediatric and adolescent dermatology at Rady Children's Hospital-San Diego and INTEGUMENT study investigator. "In clinical trials, ZORYVE cream 0.05% rapidly improved the severity and extent of eczema (atopic dermatitis) signs and symptoms, with approximately 40% of children achieving a 75% improvement from baseline as measured by EASI, and more than one-third (35%) achieving a clinically meaningful improvement in itch intensity, both in only four weeks. With this approval, healthcare providers and families have an effective new treatment option for young children with atopic dermatitis."

In the United States, approximately 1.8 million children between the ages of 2 to 5 with atopic dermatitis are treated with a topical product. Itch is one of the most burdensome symptoms of the disease, and children can be caught in an itch-scratch cycle that can worsen their symptoms.

"Young children are particularly vulnerable to the bothersome symptoms of atopic dermatitis, because their immune system and skin barrier are less developed than those of older children and adults," said Korey Capozza, MPH, founder and executive director at Global Parents of Eczema Research. "This condition doesn't just affect the child's skin — it can affect the whole family by causing sleep disruption, emotional distress, and social isolation. We are excited to see advancements in treatment options for the millions of children and families who are impacted by this disease."

"ZORYVE cream was intentionally formulated to address the critical unmet need in atopic dermatitis care, and it provides a safe, effective alternative to steroid treatments, targeting the underlying inflammation that drives disease activity. Notably, ZORYVE does not include ingredients known to compromise the skin barrier, which is especially important for young children with atopic dermatitis," said Frank Watanabe, president and chief executive officer of Arcutis. "ZORYVE provides patients and their families with a treatment option for long-term, continuous use, helping maintain clear skin and limiting cumulative topical steroid exposure."

"Seeing our daughter, Kylie, struggle with atopic dermatitis for so long was heartbreaking, but it also took a toll on the whole family. Kylie was uncomfortable, especially at night, which kept the family up and wore on our energy. I felt helpless," said Melissa Walters, caregiver of a child who participated in the INTEGUMENT-PED and INTEGUMENT-OLE studies. "It was frustrating to feel like we were stuck in a cycle of short-term fixes. We enrolled Kylie in the ZORYVE cream clinical trial when she was 2, which resulted in her skin improving and becoming clear. I want to share our story to empower other parents to advocate for their children and talk to their healthcare provider about treatment options that can be used long term."

The latest approval of ZORYVE cream 0.05% represents the sixth FDA approval for the ZORYVE portfolio in just over three years. Arcutis intends to make ZORYVE cream 0.05% widely available via key wholesaler and pharmacy channels as a new treatment option by the end of October 2025.

The Company 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‡.

For more information on ZORYVE, including full Prescribing Information, please visit http://www.zoryvehcp.com/.

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

Clinical Data

The FDA approval of ZORYVE cream 0.05% is based on results from the INTEGUMENT-PED Phase 3 trial (INterventional Trial EvaluatinG roflUMilast cream for the treatmENt of aTopic dermatitis), the INTEGUMENT-OLE long-term extension study, and a Phase 1 pharmacokinetic study. In clinical trials, ZORYVE demonstrated rapid clearance of atopic dermatitis, with positive results across all efficacy endpoints, and was safe and well tolerated.

INTEGUMENT-PED was a randomized, double-blind, vehicle-controlled, parallel-group study, that evaluated ZORYVE cream or vehicle once-daily for 4 weeks in 652 children ages 2 to 5 years (n=437 treated with ZORYVE cream, n=215 vehicle). INTEGUMENT-OLE was a Phase 3, multicenter, open-label extension study of the long-term safety and efficacy of ZORYVE cream 0.15% in adults and children ages 6 years and older with atopic dermatitis and ZORYVE cream 0.05% in children ages 2 to 5 years with atopic dermatitis. A total of 658 children and adults from INTEGUMENT-1 and -2 and 562 children from INTEGUMENT-PED enrolled in the INTEGUMENT-OLE study.

In the INTEGUMENT-PED trial, ZORYVE demonstrated rapid disease clearance, with data showing significant improvements as early as Week 1. At Week 4, 25.4% of children treated with ZORYVE cream 0.05% achieved vIGA-AD Success, defined as a validated Investigator Global Assessment – Atopic Dermatitis (vIGA-AD) score of 'Clear' or 'Almost Clear', plus a 2-grade improvement from baseline, compared to 10.7% of children treated with vehicle (P<0.0001).

The study also met all pre-determined secondary endpoints, with improvements seen across all time points, including vIGA-AD of 'Clear' and 'Almost Clear' at Week 1. Additionally, 39.4% of children using ZORYVE cream achieved a 75% reduction in Eczema Area and Severity Index (EASI-75) at Week 4 compared to 20% using vehicle, with differences observed as early as Week 1 (exploratory endpoint).

ZORYVE was also shown to reduce itch at Week 4, with some caregivers reporting less itching within 24 hours after first application. In an exploratory analysis, over one-third of the children who had a baseline Worst Itch Numeric Scale (WI-NRS) score ≥4 (as reported by the caregiver) achieved a four-point reduction in WI-NRS at Week 4 (vs. 18% for vehicle-treated children [nominal P=0.0002]).

ZORYVE cream 0.05% was well-tolerated in the pivotal studies. The most common adverse reactions reported in the clinical trials of ZORYVE cream 0.05% were upper respiratory tract infection, diarrhea, vomiting, rhinitis, conjunctivitis, and headache.

In INTEGUMENT-OLE, ZORYVE treatment continued for up to 56 weeks. Not only was efficacy maintained over time, but it continued to improve, with 71.9% of participants who rolled over from the ZORYVE cream 0.05% treatment arm in the INTEGUMENT-PED trial achieving 75% improvement from baseline in EASI after 56 weeks of treatment.

Starting at Week 4 of INTEGUMENT-OLE, participants who achieved a vIGA-AD score of Clear (0), switched to proactive twice-weekly application (170 participants; 30.2% of those treated with ZORYVE cream 0.05%). 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 with ZORYVE cream 0.15%.

The safety profile of ZORYVE cream 0.05% was generally consistent with continued treatment in INTEGUMENT-OLE.

About Atopic Dermatitis
Atopic dermatitis is the most common type of eczema, affecting approximately 9.6 million children and 16.5 million adults in the United States. Atopic dermatitis is a chronic, relapsing, and genetically predisposed inflammatory skin disease that has unique clinical presentations across the lifespan. The disease typically appears as a red, intensely itchy rash that can occur anywhere on the body. It presents differently in infants, children, and adults. Younger children typically have more widespread atopic dermatitis, including on the face, neck, and areas around the knees and elbows.

Atopic dermatitis is often initially diagnosed during childhood with approximately 90% of people with atopic dermatitis developing symptoms by age 5. Pediatric atopic dermatitis can negatively impact the entire family by significantly disrupting sleep, increasing the risk of skin infections, and leading to developmental and emotional strain for both the child and caregivers.

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 an advanced 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 was awarded by *Allure* with a prestigious "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% is approved by the FDA for the topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older. ZORYVE 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." 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 June 26, 2025. ZORYVE cream 0.05% is approved by the FDA for the topical treatment of mild to moderate atopic dermatitis in pediatric patients 2 to 5 years of age. ZORYVE topical foam 0.3% is approved by the FDA for the treatment of plaque psoriasis of the scalp and body in patients 12 years of age and older, as well as for seborrheic dermatitis in patients 9 years of age and older. 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.

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 6 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 (≥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%).

The most common adverse reactions reported (≥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 (≥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 (≥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 cream and full Prescribing Information for ZORYVE foam.

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

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 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 potential real-world use results of ZORYVE cream, including younger children of ages 2 to 5 years old, and the Company's expected timing and plan to commercially launch ZORYVE cream 0.05% by the end of October. 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.