



## U.S. FDA Accepts Supplemental New Drug Application for Arcutis' ZORYVE® (roflumilast) Cream 0.05% for the Treatment of Children Aged 2 to 5 with Mild to Moderate Atopic Dermatitis

February 26, 2025

- U.S. Food and Drug Administration (FDA) has set a Prescription Drug User Fee Act (PDUFA) target action date of October 13, 2025
- Application supported by positive efficacy and safety data from pivotal Phase 3 trial, pivotal long-term extension study, and Phase 1 pharmacokinetic study
- If approved, ZORYVE cream 0.05% will be a new topical therapy option for approximately 1.8 million children aged 2 to 5 with atopic dermatitis (AD) in the United States

WESTLAKE VILLAGE, Calif., Feb. 26, 2025 (GLOBE NEWSWIRE) -- **Arcutis Biotherapeutics, Inc.** (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced the FDA's acceptance of a supplemental New Drug Application (sNDA) for ZORYVE (roflumilast) cream 0.05%, a once-daily, next generation phosphodiesterase-4 (PDE4) inhibitor, for the topical treatment of mild to moderate AD in children 2 to 5 years old. The FDA has set a PDUFA target action date of October 13, 2025 for this application.

"In clinical trials, investigational ZORYVE cream 0.05% has shown significant positive results in treating AD in children 2 to 5 years old. The data highlight the efficacy of the cream, along with its favorable safety and tolerability profile, which are critical when prescribing a long-term treatment for children with AD," said Mercedes E. Gonzalez, MD, medical director of Pediatric Skin Research, LLC, and INTEGUMENT PED clinical trial investigator. "In children, AD often occurs on sensitive areas like the face and neck. In addition to persistent itching and scratching, AD is associated with a lower quality of life for the affected child and caregiver. If approved, ZORYVE cream 0.05% will provide a new treatment option that offers long-term relief and can help alleviate the disease burden for children and their caregivers."

Atopic dermatitis is a chronic, genetically predisposed, relapsing inflammatory skin disease that has unique clinical presentations across the lifespan. The disease may appear as a red, intensely itchy rash that can occur anywhere on the body. It may present differently in infants, children, and adults.

"Topical treatments prescribed to young AD patients today can have significant shortcomings, which lead to difficult trade-offs between efficacy, safety, and tolerability. Our clinical trials demonstrate that investigational ZORYVE cream 0.05% effectively relieves the itchy rash of AD in these very young children, with a safe and tolerable profile that dermatology clinicians trust from their experience with our ZORYVE portfolio," said Frank Watanabe, president and CEO of Arcutis. "Our commitment to helping people with immune-mediated dermatological diseases is underscored by our efforts to provide an alternative to steroids with a new targeted topical therapy option with the potential to advance the standard of care for the approximately 1.8 million children between the ages of 2 and 5 living with AD."

The sNDA is supported by positive results from the pivotal INTEGUMENT-PED Phase 3 trial (4 weeks), the INTEGUMENT-OLE long-term extension study (up to 52 weeks), as well as a Phase 1 pharmacokinetic study.

INTEGUMENT-PED, the pediatric pivotal vehicle-controlled Phase 3 trial, enrolled 652 children from 2 to 5 years of age, with an AD Body Surface Area (BSA) ranging from 3% to 82% and a mean BSA of 22%. Key trial results include:

- The data showed 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 significant improvements seen across all time points, including vIGA-AD success and vIGA-AD of 'Clear' and 'Almost Clear' at Week 1.
- ZORYVE also helped rapidly reduce the itch, with over a third of the children who had a baseline Worst Itch Numeric Scale (WI-NRS) score  $\geq 4$  (as reported by the caregiver) achieving a four-point reduction in WI-NRS at Week 4 (vs. 18.0% for vehicle-treated children [nominal P=0.0002]).

ZORYVE cream 0.05% was well-tolerated in the studies. Overall, the incidence of adverse events (AEs) in INTEGUMENT-PED was low. The safety profile observed in 2- to 5-year-old pediatric subjects treated with ZORYVE cream 0.05% during the trial was consistent with the favorable safety profile established in adults and older pediatric subjects treated with ZORYVE cream 0.15% with mild to moderate AD.

### About ZORYVE (roflumilast) Cream

Roflumilast cream is a next generation topical 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. Roflumilast cream 0.3% (ZORYVE®) is approved by the FDA for the topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older. Roflumilast cream 0.15% (ZORYVE®) is approved by the FDA for the topical treatment of mild to moderate AD 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."

### INDICATIONS

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).

The most common adverse reactions ( $\geq 1\%$ ) 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 ( $\geq 1\%$ ) 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](#).

#### **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 including three FDA approved products that harness our unique dermatology development platform coupled with our dermatology expertise to build differentiated therapies against biologically validated targets. Arcutis' dermatology development platform includes a robust pipeline with multiple clinical programs for a range of inflammatory dermatological conditions including scalp and body psoriasis, AD, and alopecia areata. For more information, visit [www.arcutis.com](http://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 of real-world use results of ZORYVE cream in AD in children aged 2 to 5, and the potential for ZORYVE cream to advance the standard of care in AD and other inflammatory dermatological conditions. 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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