FDA Accepts Supplemental New Drug Application for Arcutis' ZORYVE® (roflumilast) Cream 0.3% for the Treatment of Plaque Psoriasis in Children Ages 2 to 5

November 17, 2025

- Prescription Drug User Fee Act (PDUFA) target action date set for June 29, 2026
- If approved, ZORYVE cream 0.3% would be the first and only topical PDE4 inhibitor indicated for plaque psoriasis in children as young as 2

WESTLAKE VILLAGE, Calif., Nov. 17, 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 acceptance of a supplemental New Drug Application (sNDA) for ZORYVE® (roflumilast) cream 0.3%, a once-daily, advanced targeted topical phosphodiesterase-4 (PDE4) inhibitor, to expand the indication for the topical treatment of plaque psoriasis to include children 2 to 5 years old. The FDA has set a PDUFA target action date of June 29, 2026, for this application.

"Plaque psoriasis in young children can be particularly challenging to manage, as it often affects sensitive areas such as the face and intertriginous skin," said Amy Paller, MS, MD, attending physician, dermatology, Walter J. Hamlin Professor and chair of dermatology, professor of pediatrics, Northwestern University Feinberg School of Medicine. "Effective and well-tolerated treatment options that are gentle enough for these areas are critical to support long-term disease control and improve quality of life for children and their families."

"This milestone brings us closer to helping families and clinicians caring for young children with plaque psoriasis," said Frank Watanabe, president and CEO of Arcutis. "If approved, ZORYVE cream 0.3% would be the first and only topical PDE4 inhibitor indicated for children as young as two, offering a steroid-free option that delivers both efficacy and tolerability for this particularly vulnerable group. We remain deeply committed to advancing care for people of all ages living with immune-mediated skin diseases, offering innovative, advanced targeted topicals to elevate the standard of care—including children as young as age two."

ZORYVE cream 0.3% is currently approved for plaque psoriasis in adults and children down to age 6. This sNDA is supported by data from a 4-week Maximal Usage Systemic Exposure (MUSE) study in children aged 2 to 5 years with plaque psoriasis, as well as data from a long-term open-label study that included children in that age range. Results from this long-term study demonstrate consistent favorable long-term safety and tolerability as well as persistence of efficacy across all age ranges studied.

About Plaque Psoriasis
Psoriasis is a common, chronic, inflammatory skin disease that affects nearly 9 million people in the United States. Symptoms include itch, scaling, redness, flaking, and pain. On darker skin tones, plaques may appear more grayish, purplish, or brown. Psoriasis can appear anywhere on the body, including the knees, elbows, torso and thin-skinned areas like the face, genitals and intertriginous areas, which are areas where skin touches skin, such as the armpits, under the breasts, stomach folds, between the buttocks, and in the groin. In children, psoriasis more commonly affects these sensitive areas and intertriginous regions, posing treatment challenges and quality-of-life burdens for patients and families.

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, 0.3%, is indicated for topical treatment of plaque psoriasis, including intertriginous areas, 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 0.3% 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%).

Please see full Prescribing Information for ZORYVE cream.

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 0.3% for plaque psoriasis for children ages 2 to 5 years, and the potential of ZORYVE cream to advance the standard of care for plaque psoriasis 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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