FDA Approves Arcutis' ZORYVE® (roflumilast) Cream 0.3% for the Treatment of Plaque Psoriasis in Children as Young as Age 2

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- ZORYVE cream 0.3% is the first once-daily, non-steroidal therapy approved for children with plaque psoriasis as young as 2 years of age
- ZORYVE cream 0.3% is safe, effective, and well-tolerated for use anywhere on the body with no restrictions on duration of use
- Seventh FDA approval for ZORYVE in four years

WESTLAKE VILLAGE, Calif., June 29, 2026 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on 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) to expand the indication for ZORYVE® (roflumilast) cream 0.3% for the topical treatment of plaque psoriasis, including intertriginous areas, to children down to age 2. ZORYVE cream 0.3% is a once-daily, steroid-free topical that is safe, effective, and well tolerated, and is suitable for use anywhere on the body with no limitations on duration of use.

Plaque psoriasis is a chronic, immune-mediated inflammatory skin disease that can begin early in life and persist for decades. Plaque psoriasis can appear as raised, red, or discolored areas of skin covered with silvery scales.

"Young children with plaque psoriasis face unique challenges, including disease involvement on sensitive skin, such as the face and skin folds. Although topical steroids are commonly used to treat pediatric plaque psoriasis, they are not recommended on sensitive areas or for long-term, continuous use," said Lisa Swanson, MD, FAAD, board-certified pediatric dermatologist and clinical trial investigator, Ada West Dermatology. "In clinical studies, ZORYVE cream 0.3% demonstrated consistent safety and efficacy in improving the signs and symptoms of plaque psoriasis as seen in adults and adolescents, and was safe and well tolerated in children as young as age 2. This approval provides physicians and caregivers a targeted topical therapy that can be used anywhere on the body for any duration of time."

"Parents and caregivers of young children with plaque psoriasis have faced a significant treatment gap for years, with very limited options, even though this skin condition can have a profound impact on the child and the entire family," said Leah Howard, president and chief executive officer, National Psoriasis Foundation. "The FDA approval of a once-daily, steroid-free topical treatment for children as young as 2 introduces an important new treatment option for a largely overlooked population and represents a significant advancement in pediatric psoriasis care."

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

ZORYVE cream 0.3% was previously approved for the treatment of plaque psoriasis in adults and children down to age 6. The approval of the expanded indication is based on data from a 4-week Maximal Usage Systemic Exposure (MUSE) study (ARQ-151-216) evaluating ZORYVE cream 0.3% in children ages 2 to 5 years with plaque psoriasis. This open-label study assessed pharmacokinetics, safety, tolerability, and exploratory efficacy in children with plaque psoriasis involving at least 2% body surface area. Supportive long-term safety data were derived from an open-label extension study (ARQ-151-306), which evaluated the long-term safety, tolerability, and efficacy of ZORYVE cream 0.3% in individuals ages 2 to 5 years with plaque psoriasis for up to 24 weeks of treatment. Results demonstrated safety and efficacy profiles that were generally consistent with those observed in the DERMIS-1 and DERMIS-2 pivotal Phase 3 trials in adolescents and adults.

"Children with plaque psoriasis under age 6 have historically had few treatment options that are appropriate for long-term use, forcing families and clinicians to navigate care for a chronic, progressive skin condition with limited choices," said Frank Watanabe, president and chief executive officer of Arcutis. "ZORYVE cream 0.3%, a potent and selective PDE4 inhibitor, directly addresses this treatment gap and is the first once-daily steroid-free treatment for plaque psoriasis approved down to age 2. This seventh FDA approval for ZORYVE in four years demonstrates Arcutis' commitment to delivering meaningful innovation to the youngest children and their families."

ZORYVE cream is widely available today via key wholesaler and dermatology pharmacy channels. Arcutis is committed to ensuring predictable access across the ZORYVE portfolio through a simplified copay and fulfillment process. The ZORYVE® Direct Program supports patients who have been prescribed ZORYVE by helping navigate the insurance process, assisting with adherence, and providing access to the ZORYVE Direct Savings Card Program to help reduce out-of-pocket costs for eligible commercially insured patients.† The Company also offers the Arcutis Cares™ patient assistance program, which provides ZORYVE at no cost to financially eligible patients who are uninsured or underinsured.‡

For more information about ZORYVE, including full Prescribing Information, please visit www.zoryve.com.

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, and flaking. 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 area.

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 and recommendations. ZORYVE was 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 adults with mild to moderate atopic dermatitis, according to updated guidelines released in 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. In 2024, ZORYVE cream 0.15% was awarded *Glamour's* Beauty and Wellness Award for "Best Eczema Product."

INDICATIONS
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.

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, 0.05%, is indicated for topical treatment of mild to moderate atopic dermatitis in pediatric patients 2 to 5 years of age.

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 0.3% 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%).

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 0.05% 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%).

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 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 real-world use results of ZORYVE cream 0.3%, and the potential for ZORYVE cream to advance the standard of care in plaque psoriasis including this young patient population. 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.

† 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.

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