



Arcutis Submits Supplemental New Drug Application for ZORYVE® (roflumilast) Cream 0.3% to Expand Indication for Treatment of Plaque Psoriasis in Children Ages 2 to 5

September 3, 2025

- If approved, ZORYVE cream would be the first and only topical PDE4 inhibitor indicated for plaque psoriasis in children as young as 2, offering patients and caregivers an important alternative to topical steroids and vitamin-D analogs
- ZORYVE cream is uniquely formulated to be effective, safe, and well tolerated for all areas of the body, including sensitive areas such as intertriginous skin, where plaque psoriasis often presents in children

WESTLAKE VILLAGE, Calif., Sept. 03, 2025 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced the submission of a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) to expand the indication of ZORYVE® (roflumilast) cream 0.3% for the treatment of plaque psoriasis in children down to the age of 2. If approved, ZORYVE cream 0.3% would be the first and only topical PDE4 inhibitor treatment indicated for plaque psoriasis in children down to age 2.

"Today, there are very limited FDA-approved treatment options for plaque psoriasis for children under 6, who often present with disease on sensitive skin such as the face and intertriginous areas. There is a significant unmet need for non-steroidal options that can effectively treat plaque psoriasis over the long-term," said Adelaide Hebert, MD, professor and chief of pediatric dermatology at UTHealth Houston. "If approved, investigational ZORYVE cream could be an important first-line treatment option for children as young as age 2."

Plaque psoriasis is the most common form of psoriasis in young children and presents with similar clinical features to those seen in adults. However, in children — particularly those under 6 — psoriasis often appears in sensitive areas, such as the face or intertriginous areas, increasing the challenge of safe long-term management.

ZORYVE cream is a once-daily, steroid-free, non-greasy cream that does not include sensitizing excipients or irritants such as propylene glycol, polyethylene glycol, ethanol, or fragrances. It is the only topical treatment specifically indicated for intertriginous psoriasis and has demonstrated efficacy, safety, and tolerability across adults and children.

"This submission represents another important step forward in our goal to establish ZORYVE as foundational therapy for young children suffering with inflammatory skin diseases," said Frank Watanabe, president and CEO at Arcutis. "Historically, many treatments for inflammatory skin diseases were not studied in children, creating challenges for the clinicians who treat these vulnerable patients. Arcutis is committed to helping to address this gap in treatment through conducting trials of ZORYVE in pediatric patients across a range of inflammatory skin diseases."

ZORYVE cream 0.3% is currently approved for plaque psoriasis in adults and children down to age 6. The 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. Results from the long-term study demonstrate consistent favorable long-term safety and tolerability as well as persistence of efficacy across the 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 area. 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 is a next-generation, highly potent and selective 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.

ZORYVE (roflumilast) 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 (roflumilast) 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." ZORYVE (roflumilast) topical foam 0.3% is uniquely formulated for use anywhere on the body, including hair-bearing areas, and is indicated for treatment of plaque psoriasis of the scalp and body in patients 12 years of age and older, as well as seborrheic dermatitis in patients 9 years of age and older. Recently, 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, 0.3%, 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.

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 ($\geq 1\%$) 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%).

The most common adverse reactions ($\geq 1\%$) for ZORYVE foam 0.3% for plaque psoriasis include headache (3.1%), diarrhea (2.5%), nausea (1.7%), and nasopharyngitis (1.3%).

The most common adverse reactions ($\geq 1\%$) for ZORYVE foam 0.3% for seborrheic dermatitis include 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.

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](#).

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 for ZORYVE cream 0.3% as a treatment for plaque psoriasis in children 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.

Contacts

Media

Amanda Sheldon, Head of Corporate Communications
media@arcutis.com

Investors

Brian Schoelkopf, Head of Investor Relations
ir@arcutis.com