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

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- ZORYVE cream 0.05% provided meaningful disease clearance and rapid reduction in itch in pivotal trials
- Roflumilast cream was well tolerated and demonstrated a favorable safety and tolerability profile for up to 56 weeks of treatment
- Approximately 1.8 million children with atopic dermatitis (AD) aged 2 to 5 are topically treated in the United States

WESTLAKE VILLAGE, Calif., Dec. 16, 2024 (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) 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.

“When choosing a therapy for very young children living with AD, healthcare providers and caregivers have to account for unique considerations for pediatric patients, including sensitive skin, and select a medication that is appropriate for long-term use by a child with a chronic skin condition. Data from the pivotal trial demonstrated that roflumilast cream 0.05% provided consistent and rapid relief, and was well-tolerated,” said Rocco Serrao, MD, FAAD, of DOCS Dermatology and INTEGUMENT-PED and INTEGUMENT-OLE investigator. “If approved, roflumilast cream 0.05% would offer a new topical option with the potential to advance the standard of care for these young patients, offering fast relief to the children and their families from the onerous symptoms of AD.”

AD is a chronic, genetically predisposed, relapsing inflammatory skin disease that presents across the lifespan. The disease may appear as a red, intensely itchy rash that can occur anywhere on the body and may present differently in children and adults. Pediatric AD can negatively impact the quality of life of the child as well as their family or caregivers.

“Parents, caregivers, and healthcare professionals need to feel confident in their treatment plan. Our clinical development program for ZORYVE reinforces the well-established efficacy, safety, and tolerability profile of roflumilast cream, which was designed to deliver drug without disrupting the skin barrier or using sensitizing excipients and irritants. This lower concentration of roflumilast cream was intentionally formulated for the needs of younger children with AD and demonstrates our commitment to serving this vulnerable patient population,” said Frank Watanabe, president and CEO of Arcutis. “We look forward to the opportunity to offer ZORYVE cream 0.05%, if approved, as a new topical therapy for the 1.8 million children between the ages of 2 to 5 with AD and their families.”

The sNDA is supported by positive results from one pivotal Phase 3 trial, one pivotal long-term extension study, as well as a Phase 1 pharmacokinetic study. The INTEGUMENT-PED vehicle-controlled, pivotal Phase 3 trial enrolled 652 children 2 to 5 years of age, with a mean AD Body Surface Area (BSA) of 22% overall, and ranging from 3% to 82%. In the study, at Week 4, 25.4% of children treated with roflumilast 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 ($P<0.0001$), with significant improvements seen as early as Week 1. All secondary endpoints were also met, with significant improvements seen across all time points, including vIGA-AD success and vIGA-AD of ‘Clear’ and ‘Almost Clear’ at Week 1. In addition, 35.3% of children treated with roflumilast cream 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. 18.0% for vehicle-treated children [nominal $P=0.0002$]).

Roflumilast cream 0.05% was well-tolerated. Overall, 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. The most frequent adverse events occurring in the roflumilast arm greater than vehicle (≥2%) included upper respiratory tract infection, diarrhea, and vomiting.

The submission is also supported by data from the INTEGUMENT-OLE open-label extension study in which patients ages 2 to 5 (n = 562) were treated for up to 52 weeks.

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 (≥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 (≥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 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 27, 2024, as well as any subsequent filings with the SEC. You should not place undue reliance on any forward-looking statements in this press release. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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