Arcutis Presents Late-Breaking Data From INTEGUMENT-PED Phase 3 Trial of Roflumilast Cream 0.05% in Atopic Dermatitis in Children Ages 2 to 5 at the American Academy of Dermatology Annual Meeting

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- Investigational roflumilast cream 0.05% met the primary endpoint and all secondary endpoints, showing significant improvement across multiple efficacy endpoints as early as Week 1
- 39.4% of children treated with roflumilast cream 0.05% achieved a 75% improvement in Eczema Area and Severity Index (EASI-75), a key secondary endpoint
- New data highlight rapid and significant reduction in itch as early as 24 hours following first application of roflumilast cream 0.05% based on daily Worst Itch Numeric Scale (WI-NRS)
- New data show 35.4% of children treated with roflumilast cream 0.05% achieved a validated Investigator Global Assessment – Atopic Dermatitis (vIGA-AD) score of 'clear' or 'almost clear' at Week 4, with significant improvements seen as early as Week 1
- Results for roflumilast cream 0.05%, show consistent efficacy and favorable safety and tolerability profile from the INTEGUMENT-1 and INTEGUMENT-2 pivotal trials

SAN DIEGO, March 10, 2024 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today presented in a late-breaking clinical trial session at the American Academy of Dermatology (AAD) annual meeting (San Diego, CA, March 8 – 12) new data from its INTEGUMENT-PED pivotal Phase 3 study of investigational roflumilast cream 0.05% in children 2 to 5 years of age with mild to moderate atopic dermatitis. The study found that treatment with once-daily, steroid-free roflumilast cream 0.05% resulted in significant improvements in atopic dermatitis across multiple efficacy endpoints and all timepoints, including disease clearance as early as Week 1 and reduction in itch in the first 24 hours following application.

Results showed 25.4% of children treated with roflumilast cream 0.05% achieved the primary endpoint of IGA Success, defined as vIGA-AD score of 'clear' or 'almost clear' plus a 2-grade improvement from baseline at Week 4, compared to 10.7% treated with the vehicle (P<0.0001), with significant improvements also seen at Week 1 and Week 2. In the study, 39.4% of children treated with roflumilast cream 0.05% achieved a 75% improvement in EASI (EASI-75) at Week 4 compared to 20.6% treated with vehicle (P<0.0001).

"For the pediatric patient population, tradeoffs between efficacy, tolerability, and safety are critical aspects of atopic dermatitis treatment decisions. In addition, tolerability is paramount, and if there are problems with tolerability, there is a hurdle for adherence," said Lawrence F. Eichenfield, MD, professor of dermatology and pediatrics and vice-chair of the department of dermatology at UC San Diego School of Medicine, and study investigator. "These tradeoffs are further amplified in young children, which is why having a well-designed formulation that doesn't disrupt the skin barrier benefits the patient and decreases the concerns of caregivers. The results from this study of once-daily application of roflumilast cream 0.05% in patients 2 to 5 years old are consistent with the findings from the INTEGUMENT-1 and INTEGUMENT-2 studies of patients down to the age of 6. If approved, this profile will be a welcome, easily adopted option for patients and clinicians alike."

Roflumilast cream is an investigational once-daily, steroid-free topical cream formulated to deliver drug without disrupting the skin barrier. INTEGUMENT-PED enrolled 652 children ages 2 to 5, with a mean Body Surface Area of 22% overall, and a range from 3% to 82%. The data reinforces the well-established efficacy, safety, and tolerability profile of roflumilast cream in atopic dermatitis across the INTEGUMENT program.

New data highlighted in the session included 35.4% of children treated with roflumilast cream achieved vIGA-AD clear (0) or almost clear (1) compared to 14.6% of vehicle (P<0.0001) at the end of the study (Week 4), with improvements seen as early as Week 1. In addition, the data show improvement in itch with roflumilast cream 0.05% as early as 24 hours following first application, based on LS mean change from baseline in daily WI-NRS score (P=0.0014 vs vehicle).

"We are pleased to present these data from our pivotal Phase 3 INTEGUMENT-PED study of roflumilast cream in children aged 2 through 5, which provide strong support for the safety and efficacy in this young age group and are consistent with the results with roflumilast cream across our atopic dermatitis development program," said Patrick Burnett, MD, PhD, FAAD, chief medical officer, Arcutis. "Roflumilast cream 0.05% was also shown to be well-tolerated in young children as demonstrated by both investigator and patient-reported outcomes. We know that there is a significant unmet need for safe, tolerable, and efficacious topical treatments for this young patient population, and look forward to providing meaningful innovation through the continued development of roflumilast cream."

Roflumilast cream 0.05% was well tolerated. The incidence of Treatment Emergent Adverse Events (TEAEs) was low, and the only adverse event occurring in ≥3% of subjects in either active- or vehicle-arm was upper respiratory tract infection. The most frequent adverse events in the roflumilast arm (≥2%) included pyrexia, diarrhea, and vomiting. Local tolerability was also favorable, with application site pain only being reported in 1.6% of roflumilast-treated participants vs.1.9% for the vehicle.

About INTEGUMENT-PED

The "**IN**terventional **T**rial **E**valuatin**G** rofl**UM**ilast cream for the treatm**EN**t of a**T**opic dermatitis in **PED**iatric patients" (INTEGUMENT-PED) was a Phase 3, parallel group, double blind, vehicle-controlled trial in which roflumilast cream 0.05% or vehicle was applied once daily for four weeks to children 2 to 5 years of age with mild to moderate atopic dermatitis. No moisturizers, emollients, or other products were allowed on treatment sites during the trial. A

total of 652 children were enrolled in the study. The primary endpoint was IGA Success, defined as a vIGA-AD score of ‘clear’ or ‘almost clear’ plus a 2-grade improvement from baseline at Week 4. Multiple secondary endpoints were also evaluated, including the proportion of subjects who attained at least a 75% reduction in the EASI-75 at Week 4.

About Roflumilast Cream
Roflumilast cream is a next generation topical phosphodiesterase-4 (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 Food and Drug Administration (FDA) for the topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older. Investigational roflumilast cream was evaluated at lower doses for atopic dermatitis: 0.15% for adults and children 6 years of age and older and 0.05% for children aged 2 to 5 years. Roflumilast cream 0.15% is under review at the FDA for the treatment of adults and children 6 years of age and older with a Prescription Drug User Fee Act (PDUFA) target action date of July 07, 2024. Arcutis intends to submit a supplemental new drug application (sNDA) for roflumilast cream 0.05% in ages 2 to 5 following the potential approval of roflumilast cream 0.15%.

Roflumilast cream is uniquely formulated as a non-greasy emollient cream that absorbs quickly and does not disrupt the skin barrier. In addition, roflumilast cream does not include sensitizing excipients or irritants, such as propylene glycol, polyethylene glycol, isopropyl alcohol, ethanol, or fragrances.

About ZORYVE® Cream
ZORYVE (roflumilast) cream is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in 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%) 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%).

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 two 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, atopic dermatitis, and alopecia areata. For more information, visit www.arcutis.com or follow Arcutis on LinkedIn, Facebook, 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 and timing for roflumilast cream to be approved by the FDA for the treatment of adults and children with atopic dermatitis, the potential of real-world use results of roflumilast cream, and the potential for roflumilast cream to advance the standard of care in atopic dermatitis 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 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.

Contacts:
Media
Amanda Sheldon, Head of Corporate Communications
asheldon@arcutis.com

Investors
Latha Vairavan, Vice President, Finance and Investor Relations
lvairavan@arcutis.com

Derek Cole
Investor Relations Advisory Solutions
derek.cole@iradvisory.com