Arcutis Initiates Phase 3 Clinical Trial of Topical Roflumilast Cream (ARQ-151) as a Potential Treatment for Atopic Dermatitis in Pediatric Patients Between the Ages of Two and Five Years

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- Roflumilast cream potential “Best in Class” topical PDE4 inhibitor
- Atopic dermatitis affects approximately 19 million patients in the U.S.
- The Company anticipates topline data in the second half of 2022

WESTLAKE VILLAGE, Calif., April 12, 2021 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a late-stage biopharmaceutical company focused on developing and commercializing treatments for unmet needs in immune-mediated dermatological diseases and conditions, or immuno-dermatology, today announced it initiated a pivotal Phase 3 clinical trial evaluating topical roflumilast cream (ARQ-151) as a potential treatment for mild-to-moderate atopic dermatitis (AD) in patients between the ages of 2 and 5 years old. Roflumilast cream is a once daily topical formulation of roflumilast, a highly potent and selective phosphodiesterase type 4 inhibitor (PDE4), which the Company is developing for plaque psoriasis and AD.

“Young children suffering from atopic dermatitis often struggle with intense, persistent itching that can lead to damage caused by scratching, and that can negatively impact quality of life for both the child and the caregiver,” said Patrick Burnett, M.D., Ph.D., FAAD, Arcutis’ Chief Medical Officer. “Since the majority of atopic dermatitis patients are children, safety is particularly important. We are pleased to initiate this pivotal Phase 3 trial because we believe topical roflumilast has the potential to eliminate the need to compromise between safety, tolerability, and efficacy. In clinical trials, roflumilast cream has demonstrated a favorable safety and tolerability profile, and importantly, unlike steroids, it is safe to use chronically. In a previous Phase 2 trial, topical roflumilast has also shown encouraging efficacy in adult patients with atopic dermatitis. If approved, roflumilast cream may offer an additional treatment option to physicians and parents with otherwise limited choices.”

The “INterventional Trial EvaluatinG roflUMilast cream for the treatmENt of aTopic dermatitis in PEDiatric patients” (or INTEGUMENT-PED) is a Phase 3, parallel group, double blind, vehicle-controlled trial in which roflumilast cream 0.05% or vehicle is applied once daily for 4 weeks to patients between the ages of 2 and 5 years old with mild-to-moderate AD involving ≥3% body surface area (excluding the scalp, palms, soles).

In the trial, approximately 650 subjects will be randomized 2:1 to either roflumilast cream 0.05% or matching vehicle cream. The primary endpoint of the trial is Investigator Global Assessment (IGA) 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 at Week 4. Multiple secondary endpoints will also be evaluated, including itch as measured by the Worst Itch-Numerical Rating Scale (WI-NRS) as well as the proportion of subjects who attain at least a 75% reduction in the Eczema Area and Severity Index (EASI-75) at Week 4. The Company anticipates topline data from INTEGUMENT-PED in the second half of 2022.

Arcutis recently initiated two other pivotal Phase 3 trials (INTEGUMENT-1 and -2), which are identical Phase 3, parallel group, double blind, vehicle-controlled trials in which roflumilast cream 0.15% or vehicle is applied once daily for 4 weeks to subjects 6 years of age and older with mild to moderate AD involving ≥3% body surface area.

About Atopic Dermatitis
Atopic dermatitis (AD) is the most common type of eczema, occurring in approximately 6% of the U.S. population. AD is characterized by a defect in the skin barrier, which allows allergens and other irritants to enter the skin, leading to an immune reaction and inflammation. This reaction produces a red, itchy rash, most frequently occurring on the face, arms and legs, and the rash can cover significant areas of the body, in some cases half of the body or more. Disease onset is most common by 5 years of age, and the Company estimates that approximately 60% of patients suffering from AD are pediatric patients. The rash causes significant pruritus (itching), which can lead to skin damage caused by scratching or rubbing. Given that most of the patients are pediatric, the safety and tolerability of AD therapies is paramount.

About Topical Roflumilast Cream
Roflumilast Cream is a topical cream formulation of a highly potent and selective PDE4 inhibitor (roflumilast). Roflumilast has been approved by the U.S. Food and Drug Administration (FDA) for oral treatment to reduce the risk of exacerbations of chronic obstructive pulmonary disease (COPD) since 2011. Roflumilast has shown greater potency (25- to 300-fold) than the two other FDA-approved PDE4 inhibitors. PDE4 is an intracellular enzyme that increases the production of pro-inflammatory mediators and decreases production of anti-inflammatory mediators and has been implicated in a wide range of inflammatory diseases including psoriasis, eczema, and COPD. PDE4 is an established target in dermatology, and other PDE4 inhibitors have been approved by the FDA for the topical treatment of atopic dermatitis or the systemic treatment of plaque psoriasis.

About Arcutis - Bioscience, applied to the skin.
Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a late-stage biopharmaceutical company focused on developing and commercializing treatments for unmet needs in immune-mediated dermatological diseases and conditions, or immuno-dermatology. The Company is leveraging recent advances in immunology and inflammation to develop differentiated therapies against biologically validated targets to solve persistent treatment challenges in serious diseases of the skin. Arcutis’ robust pipeline includes four novel drug candidates currently in development for a range of inflammatory dermatological conditions. The Company’s lead product candidate, topical roflumilast, has the potential to become the standard of care for plaque psoriasis, atopic dermatitis, scalp psoriasis, and seborrheic dermatitis. For more information, visit www.arcutis.com or follow the company on LinkedIn and Twitter.

Forward Looking Statements
This press release contains "forward-looking" statements, including, among others, statements regarding roflumilast cream’s potential as a treatment for atopic dermatitis; and expectations with regard to the timing of clinical data anticipated in the second half of 2022. These statements involve

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 and you should not place undue reliance on our forward-looking statements. Risks and uncertainties that may cause our actual results to differ include risks inherent in the clinical development process and regulatory approval process, the timing of regulatory filings, and our ability to defend our intellectual property. For a further description of the risks and uncertainties applicable to our business, see the "Risk Factors" section of our Form 10-K filed with U.S. Securities and Exchange Commission (SEC) on February 16, 2021, as well as any subsequent filings with the SEC. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

Investors and Media:
Heather Rowe Armstrong
Vice President, Investor Relations & Corporate Communications
harmstrong@arcutis.com
805-418-5006, Ext. 740