Arcutis Initiates Pivotal Phase 3 Clinical Trials Evaluating Topical Roflumilast Cream (ARQ-151) as a Potential Treatment for Atopic Dermatitis

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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., Jan. 13, 2021 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a medical dermatology company developing innovative treatments for patients with immune-mediated dermatological diseases and conditions, today announced that it has commenced pivotal Phase 3 clinical trials evaluating topical roflumilast cream (ARQ-151) as a potential treatment for atopic dermatitis (AD). 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.

“More than 19 million people in the U.S. suffer from atopic dermatitis, of which at least 60 percent are young children, thereby making safety and tolerability particularly important in this disease,” said Patrick Burnett, M.D., Ph.D., FAAD, Arcutis’ Chief Medical Officer. “Atopic dermatitis is characterized by a defect in the skin barrier, which results in a red, itchy rash that in many cases can cover significant areas of the body. Current treatments often fall short, resulting in patients, parents and physicians having to make trade-offs between efficacy, safety and tolerability.”

Dr. Burnett continued, “We are excited to begin our pivotal Phase 3 trials in patients with atopic dermatitis. If approved, roflumilast cream would be the first once-a-day topical nonsteroidal treatment for AD, and would also offer patients a cosmetically-elegant, non-greasy formulation. In clinical trials, roflumilast cream has demonstrated a benign safety and tolerability profile, without the local tolerability or safety issues associated with many other topical AD treatments, and importantly, unlike steroids, it can safely be used chronically. We believe topical roflumilast has the potential to eliminate the need to compromise between safety, efficacy, and tolerability, and we look forward to reporting topline data in the second half of 2022.”

The “INterventional Trial EvaluatinG roflUMilast cream for the treatmENt of aTopic dermatitis” 1 and 2 (or INTEGUMENT-1 and -2) 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.

In each trial, approximately 650 subjects are planned to be randomized 2:1 to either roflumilast cream 0.15% or matching vehicle cream. The primary endpoint of both trials 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. After completing INTEGUMENT-1 or -2, subjects may be eligible to enroll in a 12-month, open label extension study (INTEGUMENT-OLE) evaluating once daily roflumilast cream. The Company anticipates topline data from INTEGUMENT-1 and -2 in the second half of 2022.

Arcutis also plans to initiate a third pivotal Phase 3 study, the “INterventional Trial EvaluatinG roflUMilast cream for the treatmENt of aTopic dermatitis in PEDiatric patients” (or INTEGUMENT-PED) shortly to evaluate roflumilast cream in subjects 2 to 5 years of age with mild to moderate AD.

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 revitalize the standard of care for plaque psoriasis, atopic dermatitis, scalp psoriasis, and seborrheic dermatitis. For more information, visit https://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-Q filed with U.S. Securities and Exchange Commission (SEC) on November 5, 2020, 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.

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