Arcutis' Roflumilast Foam Demonstrates Clinically Meaningful Results and Patient Quality of Life Improvements in Phase 2 Seborrheic Dermatitis Study

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- Previously reported data demonstrated that roflumilast foam provided statistically significant improvement in disease severity and a favorable safety and tolerability profile
- Improvement on Investigator Global Assessment (IGA) Success and itch as early as week 2, the first timepoint measured
- New patient reported quality of life data shows improvement across all emotional, symptom, and functioning domains

WESTLAKE VILLAGE, Calif., March 25, 2022 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a late-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced the presentation of results from the Phase 2 study of its investigational roflumilast foam 0.3%, a novel, once-daily non-steroidal foam for the treatment of seborrheic dermatitis, at the 2022 American Academy of Dermatology annual meeting, taking place in Boston, MA. Previously reported safety and efficacy data was recapitulated along with new patient quality of life data that showed significant improvement in all emotional, symptom, and function measures. Seborrheic dermatitis is a chronic inflammatory skin condition that impacts 10 million people in the United States.

"Most individuals with seborrheic dermatitis have involvement of the scalp, which can be painful and itchy, and have a negative impact on a patient's well-being. In addition, hair-bearing areas of the body are difficult to treat, often requiring complicated treatment regimens and multiple treatments," said Dr. Zoe Draelos, study investigator, dermatologist in High Point, North Carolina, and President, Dermatology Consulting Services, PLLC. "These data show that investigational roflumilast foam effectively improved and cleared seborrheic dermatitis, while also improving important measures in patients' quality of life."

Roflumilast foam is a once-daily topical foam formulation of a highly potent and selective phosphodiesterase type 4 (PDE4) inhibitor that Arcutis is developing particularly to treat inflammatory dermatoses in hair-bearing areas of the body such as the scalp. On the Phase 2 study's primary endpoint assessed at week 8, roflumilast foam 0.3% achieved an IGA success rate of 73.8% compared to a vehicle rate of 40.9% ($p<0.0001$). IGA success is defined as the achievement of an IGA score of 'clear' or 'almost clear' on a 5-grade scale plus at least a two-grade change from baseline.

Quality of life measurements were taken through ScalpDex, a validated scalp dermatitis-specific measurement in which patients score 23 questions across three quality of life domains: emotions, symptoms, and functioning. Patients reported significant improvements with roflumilast foam compared to vehicle on the emotions scale (-19.0 vs -10.9 $P<0.001$), symptoms scale (-25.6 vs -13.8 $P<0.0001$), as well as on the functioning scale (-16.1 vs -9.8 $P<0.05$).

"Seborrheic dermatitis is a challenging condition that impacts millions of people, and yet today patients have to resort to an arsenal of various outdated products to manage their disease," said Frank Watanabe, President and CEO of Arcutis. "Arcutis has specifically formulated roflumilast foam to address patients' needs through an effective, well tolerated, convenient, once-daily foam that is designed to be used on all areas of the body. Roflumilast foam has the potential to become the standard of care for seborrheic dermatitis."

In Arcutis' Phase 2 multi-center, multi-national, double blind, vehicle-controlled study in individuals with seborrheic dermatitis, patients were studied for 8-weeks and evaluated for the safety and efficacy of roflumilast foam 0.3% administered once-daily to affected areas on the scalp, face, and body. The Company recently announced the last subject enrolled in its pivotal Phase 3 STRATUM clinical trial of roflumilast foam in seborrheic dermatitis, with topline data results expected mid-year 2022.

About Seborrheic Dermatitis
Seborrheic dermatitis affects more than 10 million people in the United States, and is a common, chronic or recurrent inflammatory skin disease that causes red patches covered with large, greasy, flaking yellow-gray scales, and persistent itch. Seborrheic dermatitis occurs most often in areas of the body with oil-producing (sebaceous) glands, including the scalp, face (especially on the nose, eyebrows, ears, and eyelids), upper chest, and back.

About Topical Roflumilast Foam
Roflumilast foam is a once-daily topical foam formulation of roflumilast, a highly potent and selective PDE4 inhibitor, which the Company is developing for both seborrheic dermatitis and scalp and body psoriasis. 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. Arcutis has also submitted a New Drug Application (NDA) for a closely related cream formulation of topical roflumilast for the treatment of plaque psoriasis, with a Prescription Drug User Fee Act target action date of July 29, 2022. PDE4 is an intracellular enzyme that increases the production of pro-inflammatory mediators and decreases production of anti-inflammatory mediators; it has been implicated in a wide range of inflammatory diseases including psoriasis, atopic dermatitis, 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 and the systemic treatment of plaque psoriasis.

About Arcutis
Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a medical dermatology company that champions meaningful innovation to address the urgent needs of patients living with immune-mediated dermatological diseases and conditions. With a commitment to solving the most persistent patient challenges in dermatology, Arcutis harnesses 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, with one NDA under review with the FDA and three Phase 3 clinical data readouts anticipated by the end of 2022. The company's lead program, topical roflumilast, has the potential to advance the standard of care for plaque psoriasis, atopic

dermatitis, scalp psoriasis, and seborrheic dermatitis. For more information, visit www.arcutis.com or follow Arcutis on LinkedIn and Twitter.

Forward-Looking Statements
This press release contains "forward-looking" statements, including, among others, statements regarding the potential for roflumilast to be approved for the treatment of adults and adolescents with seborrheic dermatitis, the potential to use roflumilast foam over a long period of time, or chronically, the potential to use roflumilast foam anywhere on the body, including the face and scalp, and the potential for roflumilast to advance the standard of care in seborrheic dermatitis and other inflammatory dermatological conditions. 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 22, 2022, as well as our 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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