Arcutis Biotherapeutics Showcases New Roflumilast Data in Psoriasis and Seborrheic Dermatitis at American Academy of Dermatology (AAD) Virtual Meeting Experience (VMX) 2021

April 23, 2021

- *Detailed results from Phase 2b study of roflumilast foam in scalp and body psoriasis featured in late-breaking oral presentation*
- *Data demonstrate roflumilast foam was well-tolerated and improved scalp and body psoriasis as early as two weeks after treatment initiation*
- *Four additional posters feature data that support roflumilast foam for the treatment of seborrheic dermatitis and roflumilast cream for mild-to- severe chronic plaque psoriasis*

WESTLAKE VILLAGE, Calif., April 23, 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 the presentation of new data demonstrating the safety and efficacy of roflumilast foam for the treatment of scalp and body psoriasis in a late-breaking oral presentation at the American Academy of Dermatology (AAD) Virtual Meeting Experience (VMX) held on April 23-25, 2021.

The company is also showcasing data from four additional posters during the meeting, including a presentation on the safety and efficacy of roflumilast foam in the treatment of seborrheic dermatitis and three posters related to roflumilast cream in mild-to-severe chronic plaque psoriasis, including its impact on itch and use for steroid-sensitive areas. Roflumilast cream and foam are investigational once-daily, topical formulations of a highly potent and selective phosphodiesterase-4 (PDE4) inhibitor.

“Psoriasis and seborrheic dermatitis can significantly impact quality of life and are very challenging to treat, particularly long-term,” said Patrick Burnett, M.D., Ph.D., FAAD, Chief Medical Officer, Arcutis. “These new data add to the growing body of evidence supporting the potential of roflumilast, if approved, as an important, new treatment option for people affected by these chronic dermatological conditions.”

New findings from the late-breaking presentation demonstrate that roflumilast foam significantly improved both scalp and body psoriasis, with improvement as early as two weeks after treatment initiation. The primary endpoint of Scalp Investigator’s Global Assessment (S-IGA) success (clear/almost clear and ≥2-grade reduction from baseline) at week eight was achieved by 59.1% of patients receiving roflumilast foam versus 11.4% of patients receiving vehicle (P<0.0001), with 34.3% of roflumilast foam-treated and 3.4% of vehicle-treated patients rated clear at week eight. Body IGA success at week eight was achieved by 40.3% and 6.8% of patients receiving roflumilast foam and vehicle, respectively (P<0.0001).

Roflumilast foam was well-tolerated in the study. The incidence of treatment-related adverse events (TEAEs), application site adverse events (AEs), and discontinuations due to AEs were low and similar to vehicle. The most common TEAEs were application site pain (1.0% vs. 3.8%), diarrhea (1.5% vs. 0%), COVID-19 (1.5% vs. 1.9%), sinusitis (0.5% vs. 1.9%), psoriasis (0.5% vs. 1.9%), and hypertension (1.5% vs. 1.0%) for roflumilast foam and vehicle, respectively. Discontinuation due to AEs was 2.5% for roflumilast foam and 1.9% for vehicle. In the study, no patients in either group experienced any serious AEs.

“Many current treatment options for psoriasis often carry significant limitations, particularly when being used to treat body areas covered with hair, which result in poor outcomes and additional patient burden,” said lead investigator Leon Kircik, M.D., Clinical Professor of Dermatology, Icahn School of Medicine at Mount Sinai, Indiana University Medical Center, and Medical Director, Physicians Skin Care, DermResearch, and Skin Sciences, Louisville, KY. “Roflumilast once-daily foam, a novel formulation specifically designed for use on hair-bearing areas of the body like the scalp, but usable on all areas of the body, demonstrated significant benefit on both scalp and non-scalp areas. These positive results are encouraging for patients and clinicians who are desperate for new treatments that can simplify disease management, be used in all areas of the body, and ultimately improve the patient experience.”

Key findings from the other roflumilast foam and cream presentations include:

- Efficacy and Safety of Roflumilast Foam 0.3% in Patients with Seborrheic Dermatitis in a Randomized, Double-blind, Vehicle-controlled Phase 2 Study
  - Findings from this Phase 2 study demonstrated roflumilast foam is a safe, well-tolerated, and effective treatment in patients with seborrheic dermatitis. Treatment with roflumilast foam led to significant improvement in IGA Success, as well as erythema and scaling individually, and symptomatic improvement in itch in patients. Improvements in IGA Success were statistically significant at the first post-baseline visit at week two and continued through week eight. Rates of treatment-related AEs, discontinuations due to AEs, and application-site pain were low and similar to vehicle.

- Correlation of Itch Response to Roflumilast Cream with Disease Severity and Patient-Reported Outcomes in Patients with Chronic Plaque Psoriasis
  - The Multinational Assessment of Psoriasis and Psoriatic Arthritis (MAPP) survey showed that the top factor contributing to disease severity in psoriasis according to patients was itch, but according to physicians, it was location/size of lesions. Consistent with these findings, the baseline data from this Phase 2b study in patients with

chronic plaque psoriasis demonstrated that patient-reported itch was not always consistent with physician-assessed disease severity and that patients with mild disease can still experience considerable itch. In this Phase 2b study, treatment with roflumilast cream resulted in rapid and robust improvement in the severity of itch, itch-related sleep loss, and quality of life in patients with chronic plaque psoriasis.

- Roflumilast Cream Significantly Improves Chronic Plaque Psoriasis in Patients with Steroid-Sensitive Area Involvement
  - Many patients with psoriasis have plaques on difficult to treat areas such as the face or intertriginous regions. Topical corticosteroids and vitamin D derivatives must be used with caution in these areas because they can cause side effects or tolerability problems, especially with long-term use. In this Phase 2b study, roflumilast cream was well-tolerated and provided significant improvements in investigator and patient-assessed outcomes in participants with steroid-sensitive area involvement in a post-hoc analysis of the face, neck, or intertriginous areas in patients with chronic plaque psoriasis.

- The PASI-HD Improved Precision in Measuring Disease Severity in Subjects with Mild-to-Moderate Plaque Psoriasis Treated with Roflumilast Cream, a PDE4 Inhibitor
  - The Psoriasis Area and Severity Index (PASI) is the gold standard measure in psoriasis clinical trials, but lacks sensitivity where the affected area is <10% body surface area. Most patients with chronic plaque psoriasis have mild-to-moderate disease, thus a higher level of discrimination for the assessment of disease severity is needed. PASI-HD is proposed as a modification to PASI to provide higher discrimination of the effects of treatment in areas with <10% involvement. This post-hoc analysis of the Phase 2b study of roflumilast cream in patients with mild-to-moderate plaque psoriasis, demonstrated that PASI-HD is more precise as compared to PASI for scoring disease severity in areas of disease involvement <10%.

For more information, visit https://www.arcutis.com or follow the company on LinkedIn and Twitter. Join the conversation with the hashtag #AADVMX2021.

About Scalp and Body Psoriasis
Psoriasis is a common, non-contagious, immune-mediated skin disease that affects approximately 8.6 million patients in the U.S. About 90% of patients develop plaque psoriasis, which is characterized by raised, red areas of skin covered with a silver or white layer of scale. Psoriatic plaques can appear on any area of the body, but most often appear on the scalp, knees, elbows, trunk, and limbs, and are often itchy and sometimes painful.

Scalp psoriasis is a manifestation of plaque psoriasis characterized by plaques in the hair-bearing area of the scalp and sometimes extending to the forehead, back of the neck, or behind or inside the ears. Patients with scalp psoriasis commonly have plaques on other areas of the body as well. Scalp psoriasis is present in nearly half of Americans with psoriasis. As with psoriatic plaques on other parts of the body, scalp psoriasis is often itchy and sometimes painful. It can also be associated with hair loss.

About Seborrheic Dermatitis
Seborrheic dermatitis affects more than 10 million people in the U.S., 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 on the scalp, face (especially on the nose, eyebrows, ears, and eyelids), upper chest, and back.

About Topical Roflumilast Cream & Foam
Roflumilast Cream and Foam are once-daily, topical formulations of a highly potent and selective PDE4 inhibitor (roflumilast). The foam formulation is to treat inflammatory dermatoses in hair-bearing areas of the body, such as the scalp, although it is usable in all areas of the body. 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 for dermatology. 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, 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 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 the potential for roflumilast to revolutionize the standard of care in plaque psoriasis 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 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.

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