Arcutis Biotherapeutics to Showcase Long-term Safety, Efficacy, and Patient-Reported Outcomes of Roflumilast Cream for Chronic Plaque Psoriasis at Innovations in Dermatology: Virtual Spring Conference 2021

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Poster presentations highlight new data for roflumilast cream, including long-term safety and efficacy results in adults with chronic plaque psoriasis

WESTLAKE VILLAGE, Calif., March 17, 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, will present safety, efficacy, and patient-reported outcomes from its Phase 2 open-label long-term safety study investigating roflumilast 0.3% cream in adult patients with mild-to-severe chronic plaque psoriasis at the Innovations in Dermatology: Virtual Spring Conference 2021.

“Psoriasis can significantly impact all aspects of a patient’s life, including adverse physical, emotional, and social effects,” said Dr. Linda Stein Gold, MD, Henry Ford Health System and Chair, Innovations in Dermatology. “Current topical treatments for plaque psoriasis are often ineffective for long-term treatment, are not well tolerated, or are ill-suited for use in some areas of the body. We are excited to present data demonstrating that roflumilast addresses these limitations with the added benefit of a favorable long-term safety and efficacy profile.”

A poster presentation will feature new long-term efficacy and safety data on topical roflumilast 0.3% cream at 52- to 64-weeks (Dr. Linda Stein Gold). Additionally, two poster presentations will feature analyses of improved burden of signs and symptoms and improved itch severity (Dr. Leon Kircik), and itch-related sleep loss in adults with chronic plaque psoriasis (Dr. Linda Stein Gold) from the original Phase 2b study of roflumilast cream over a 12-week treatment period.

Arcutis also recently released positive topline data from the pivotal Phase 3 studies of roflumilast cream in plaque psoriasis, and plans to present the full results of those studies in the near future, as well as submit a New Drug Application later this year.

In addition to the plaque psoriasis presentations, Dr. Melinda Gooderham will present the results from the Phase 2 study of roflumilast cream 0.15% and 0.05% in patients with mild-to-moderate atopic dermatitis.

“Existing topical treatments prescribed to psoriasis patients have significant shortcomings, which lead to difficult trade-offs between efficacy, safety, and tolerability,” said Patrick Burnett, M.D., Ph.D., FAAD, Arcutis’ Chief Medical Officer. “These data reinforce our conviction that topical roflumilast, if approved by the FDA, has the potential to revolutionize the standard of care in plaque psoriasis and other inflammatory dermatological conditions by reducing the need to make such trade-offs.”

Arcutis is investigating roflumilast as a once-daily, nonsteroidal treatment for plaque psoriasis, atopic dermatitis, seborrheic dermatitis, and scalp psoriasis. Roflumilast cream is a once daily topical formulation of roflumilast, a highly potent and selective phosphodiesterase type 4 inhibitor (PDE4). Based on results from the pivotal Phase 3 studies, topical roflumilast potentially delivers efficacy comparable to the results of published clinical studies of high-potency steroid/calcipotriene or high-potency steroid/tazarotene combination products, but with safety and tolerability that supports chronic use in all areas of the body, and little or none of the local tolerability issues associated with many competitive agents.

For more information, visit the Innovations in Dermatology Spring Conference virtually and https://www.arcutis.com or follow the company on LinkedIn and Twitter.

About Plaque Psoriasis
Psoriasis is a common, non-contagious, immune-mediated skin disease that affects approximately 8.6 million patients in the United States. 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. Plaques in certain anatomical areas present particular treatment challenges, including the face, elbows and knees, scalp, and intertriginous regions such as the groin, axillae and inframammary areas.

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 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, 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 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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