Arcutis Biotherapeutics to Accelerate ARQ-151 (Topical Roflumilast Cream) into Phase 3 Trials for the Treatment of Atopic Dermatitis Following End-of-Phase 2 Meeting with FDA

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- Progression to Phase 3 clinical trials represents significant acceleration of atopic dermatitis development program
- Previously reported data demonstrated evidence that roflumilast cream provided symptomatic improvement and a favorable tolerability profile
- Roflumilast cream is a novel PDE4 inhibitor being developed as a once-daily topical cream for atopic dermatitis and psoriasis

WESTLAKE VILLAGE, Calif., Sept. 08, 2020 (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 plans to advance its program to develop ARQ-151 (topical roflumilast cream) for the treatment of atopic dermatitis into Phase 3 clinical trials following its End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA), without conducting the previously planned Phase 2b atopic dermatitis trial. The Company now anticipates initiating pivotal Phase 3 clinical trials in late 2020 or early 2021. ARQ-151 is a once-daily topical cream formulation of roflumilast, a highly potent and selective phosphodiesterase type 4 inhibitor (PDE4), which the Company is developing for atopic dermatitis and psoriasis.

“Following our interactions with the FDA, we are delighted to be able to accelerate the development of topical roflumilast cream into Phase 3 trials for the treatment of atopic dermatitis, a disease that affects almost 20 million people in the U.S., of which approximately 60% are children,” said Patrick Burnett, M.D., Ph.D., FAAD, Arcutis’ Chief Medical Officer. “Results from previous clinical trials have shown that our simple, easy-to-use, once-a-day topical roflumilast cream provided efficacy results similar to those seen with topical JAK inhibitors or mid-potency steroids while also being well tolerated, which is critical in children. By delivering efficacy that enables meaningful symptomatic improvement and a favorable safety and tolerability profile that supports chronic use for patients with atopic dermatitis, topical roflumilast has the potential to overcome the significant shortcomings of existing therapies, which could mitigate the need for dermatologists and patients to make trade-offs in efficacy, safety and tolerability.”

Roflumilast cream is a once-daily topical cream formulation of a highly potent and selective PDE4 inhibitor (roflumilast) that is under development for atopic dermatitis and psoriasis. Oral roflumilast has been approved by the U.S. Food and Drug Administration (FDA) for 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. Roflumilast cream is already undergoing Phase 3 clinical trials for the treatment of plaque psoriasis, with topline data expected in the first half of 2021.

About Atopic Dermatitis
Atopic dermatitis (AD) is the most common type of eczema, occurring in approximately six percent 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 are paramount.

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 the potential of roflumilast cream to address the unmet needs in the topical treatment of atopic dermatitis; the potential safety and efficacy of roflumilast cream; and the initiation of pivotal Phase 3 clinical trials in late 2020 or in early 2021. 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 August 11, 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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