Arcutis Announces Last Patient Completes Final Study Visit in DERMIS-1 and DERMIS-2 Pivotal Phase 3 Clinical Trials Evaluating ARQ-151 (Topical Roflumilast Cream) as a Potential Treatment for Plaque Psoriasis

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- Phase 3 trials' topline data anticipated in the first quarter of 2021 and potential New Drug Application (NDA) submission anticipated by the end of 2021
- Roflumilast cream potential "Best in Class" topical PDE4 inhibitor
- Plaque psoriasis affects approximately 8.6 million patients in the U.S.

WESTLAKE VILLAGE, Calif., Dec. 07, 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 that the last participant has completed the 8-week treatment period in DERMIS-1 and DERMIS-2, the Company's pivotal Phase 3 clinical trials evaluating ARQ-151 (topical roflumilast cream) as a potential topical treatment for plaque psoriasis.

"Plaque psoriasis affects approximately 8.6 million patients in the U.S., many of whom are desperate for new topical options that don't require them to make trade-offs," said Patrick Burnett, M.D., Ph.D., FAAD, Arcutis' Chief Medical Officer. "We are delighted to complete DERMIS-1 and DERMIS-2, our pivotal phase 3 clinical trials evaluating roflumilast cream as a potential once daily topical treatment for plaque psoriasis. If approved, we believe roflumilast cream has the potential to eliminate the need for dermatologists and patients to compromise between efficacy and safety. We anticipate announcing topline data from these trials in the first quarter of 2021 and, if positive, anticipate submission of our NDA to the FDA by the end of 2021. We are immensely grateful to the trial participants and the clinical investigators for their time and commitment to this important research effort."

Arcutis recently announced positive results from its Phase 2 long-term safety study in plaque psoriasis, which support chronic use of roflumilast cream. In addition, The New England Journal of Medicine published results from the double-blind, randomized Phase 2b study of roflumilast cream in plaque psoriasis.

The "Trials of P**DE**4 inhibition with **R**oflumilast for the **M**anagement of plaque Psorias**IS**" One and Two (or DERMIS-1 and DERMIS-2) are identical Phase 3 randomized, parallel, double-blind, vehicle-controlled, multi-national, multi-center studies in which roflumilast 0.3% cream or vehicle cream are applied once daily for 8 weeks to subjects age 2 years and above with mild, moderate or severe chronic plaque psoriasis involving between 2% and 20% body surface area. DERMIS-1 enrolled 439 subjects, and DERMIS-2 enrolled 442 subjects. The primary endpoint of the studies is Investigator Global Assessment (IGA) Success, defined as an IGA score of clear or almost clear and at least a 2-grade improvement from baseline at week 8 on the IGA score. Multiple secondary endpoints will also be evaluated, including Intertriginous IGA (I-IGA) Success, and improvements in Psoriasis Area Severity Index (PASI), itch as measured by the Worst Itch-Numerical Rating Scale (WI-NRS) and patient perceptions of symptoms as measured by the Psoriasis Symptoms Diary (PSD). The Company anticipates topline data from the Phase 3 studies in the first quarter of 2021 and, if positive, anticipates submission of its NDA to the FDA by the end of 2021.

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 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 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 psoriasis treatment; and expectations with regard to the timing of clinical data anticipated in the first quarter of 2021 and NDA submission by the end of 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 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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