Arcutis Announces First Patient Enrolled in Phase 3 Clinical Trial of Topical Roflumilast Foam (ARQ-154) as a Potential Treatment for Seborrheic Dermatitis

July 12, 2021

- Topical roflumilast potential “Best-in-Class” topical PDE4 inhibitor
- Seborrheic dermatitis affects 10 million patients in the U.S.
- Potential first new topical treatment for seborrheic dermatitis in decades
- The Company anticipates topline data in the second or third quarter of 2022

WESTLAKE VILLAGE, Calif., July 12, 2021 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a late-stage biopharmaceutical company focused on developing meaningful innovations to address the urgent needs of patients living with immune-mediated dermatological diseases and conditions, or immuno-dermatology, today announced enrollment of the first patient in its single pivotal Phase 3 clinical trial evaluating topical roflumilast foam (ARQ-154) as a potential treatment for seborrheic dermatitis. Roflumilast foam is a once-daily topical foam formulation of roflumilast, a highly potent and selective phosphodiesterase type 4 (PDE4) inhibitor, which the Company is developing for seborrheic dermatitis and scalp psoriasis.

“The symptoms of seborrheic dermatitis can have a significant, negative influence on quality of life and can cause psychological distress for millions of affected Americans. Despite that, no novel treatments have been developed for this chronic skin condition in decades, and current topical treatments frequently provide inadequate efficacy or pose safety concerns that limit their use,” said Patrick Burnett, M.D., Ph.D., FAAD, Chief Medical Officer of Arcutis. “In our Phase 2 trial, roflumilast foam was demonstrated to be an effective, safe, and well-tolerated treatment for seborrheic dermatitis. We are now pleased to initiate this single Phase 3 pivotal trial, as we believe roflumilast foam, if approved, has the potential to become a much-needed new standard of care for people with seborrheic dermatitis. Unlike most treatments, roflumilast foam is suitable for all body areas, including hair-bearing areas and the face, and does not pose the safety concerns typically seen with topical steroids.”

The STudy of Roflumilast foam Applied Topically for the redUction of seborrheic derMatitis (STRATUM) is a Phase 3, parallel group, double blind, vehicle-controlled study of the safety and efficacy of roflumilast 0.3% foam administered once-daily in approximately 450 subjects ages nine and older with moderate to severe seborrheic dermatitis. The primary endpoint of the study is the proportion of subjects achieving Investigator Global Assessment (IGA) success, defined as an IGA score of “clear” or “almost clear” plus a 2-point improvement at eight weeks. The Company announced in January 2021 that it had conducted a successful End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) and planned to initiate a single pivotal Phase 3 trial in seborrheic dermatitis.

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 Foam
Roflumilast foam is a once-daily, topical formulation of a highly potent and selective PDE4 inhibitor (roflumilast). The foam formulation was designed to treat hair-bearing areas of the body, such as the scalp, although it is usable in all areas of the body, including the face. 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; 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 seven clinical programs for a range of inflammatory dermatological conditions, with our first NDA submission anticipated by the end of 2021 and three more Phase 3 clinical data readouts anticipated over the next 18 months. The company’s lead product candidate, 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 revolutionize 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 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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