Arcutis Completes Enrollment of STRATUM Pivotal Phase 3 Trial of Topical Roflumilast Foam in Individuals with Seborrheic Dermatitis

February 1, 2022

- Topline data now anticipated in mid-year 2022, followed by a regulatory submission in first half of 2023
- A total of 457 subjects are enrolled in the STRATUM study
- Seborrheic dermatitis affects 10 million people in the U.S.

WESTLAKE VILLAGE, Calif., Feb. 01, 2022 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a late-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced the enrollment of the last subject in its STRATUM phase 3 pivotal trial for topical roflumilast foam in patients with seborrheic dermatitis. If positive, the Company expects the study to be sufficient basis to submit a New Drug Application (NDA) in the United States in first half of 2023.

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, and its use is being studied on all areas of the body, including the face.

“Individuals with seborrheic dermatitis have lacked new topical treatment options for decades, and current therapies leave much to be desired. The rapid enrollment of our Phase 3 trial highlights the need for topical treatments for seborrheic dermatitis that are suitable for all areas of the body, including the scalp and face,” said Patrick Burnett, MD, PhD, FAAD. “We are pleased to have completed enrollment in our pivotal Phase 3 study for roflumilast foam, marking another major milestone for our topical roflumilast clinical program. The STRATUM study was designed to generate robust safety, tolerability and efficacy data to support a potential regulatory filing.”

About STRATUM
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. A total of 457 subjects ages nine and older with moderate to severe seborrheic dermatitis have been enrolled in the study. 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. Top-line data results are expected in mid-year 2022. The Company announced in January 2021 that the U.S. Food and Drug Administration (FDA) had agreed that the single STRATUM study, if positive, would be sufficient basis for a New Drug Application 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 in areas of the body with oil-producing (sebaceous) glands, including 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 foam formulation of roflumilast, a highly potent and selective phosphodiesterase type 4 (PDE4) inhibitor, which the Company is developing for both seborrheic dermatitis and scalp and body psoriasis. 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. Arcutis has also filed a New Drug Application for a closely related cream formulation of topical roflumilast for the treatment of plaque psoriasis, with a Prescription Drug User Fee Act (PDUFA) action date of July 29, 2022. 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 multiple clinical programs for a range of inflammatory dermatological conditions, with one NDA under review with the FDA and three Phase 3 clinical data readouts anticipated by the end of 2022. The company’s lead program, 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 be approved for the treatment of adults and adolescents with seborrheic dermatitis, the potential to use roflumilast foam over a long period of time, or chronically, the potential to use roflumilast foam anywhere on the body, including the face and scalp, and the potential for roflumilast to advance 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 our 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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