Arcutis Completes Enrollment in INTEGUMENT-2 Pivotal Phase 3 Trial of Roflumilast Cream in Atopic Dermatitis

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- A total of 683 adults and children, age 6 years and older, have been enrolled in the INTEGUMENT-2 trial
- Topline data from both INTEGUMENT-1 and -2 trials expected by end of 2022
- Atopic dermatitis affects approximately 26 million adults and children in the United States

WESTLAKE VILLAGE, Calif., Aug. 23, 2022 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), an early commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno- dermatology, today announced the enrollment of the last subject in its INTEGUMENT-2 pivotal Phase 3 trial of roflumilast cream 0.15% in adults and children with atopic dermatitis (AD). Roflumilast cream is a once daily topical formulation of roflumilast, a highly potent and selective phosphodiesterase type 4 inhibitor (PDE4). The Company completed enrollment in an identically designed pivotal Phase 3 trial, INTEGUMENT-1, earlier in August 2022, with topline data from both trials expected by end of 2022. If successful, the Company believes that the trials will provide a sufficient basis to submit a supplemental New Drug Application (sNDA) for roflumilast cream 0.15% for the treatment of mild to moderate AD in individuals six years of age and older in 2023.

Atopic dermatitis is the most common type of eczema, affecting approximately 9.6 million children and 16.5 million adults in the United States. Topical therapies are an important treatment option for the majority of individuals who use prescription medications to treat their disease.

“We are excited to have completed enrollment in the second of two phase 3 pivotal trials with roflumilast cream 0.15% in individuals with atopic dermatitis age six years and older, just weeks after closing enrollment for INTEGUMENT-1. We are grateful to the principal investigators and the patients who have participated in these studies,” said Patrick Burnett, MD, PhD, FAAD, Chief Medical Officer at Arcutis. “We believe there is a large unmet need for a once-daily non-steroidal therapy for atopic dermatitis that is effective and well-tolerated, and investigational roflumilast cream has the potential to fill this need.”

After completing INTEGUMENT-1 and INTEGUMENT-2, individuals may be eligible to enroll in an open label extension study (INTEGUMENT-OLE) evaluating treatment with once daily roflumilast cream 0.15% for up to 12 months.

About INTEGUMENT-2
The “INterventional Trial EvaluatinG roflUMilast cream for the treatmENt of aTopic dermatitis” 2 (INTEGUMENT-2) is a Phase 3, parallel group, double blind, vehicle-controlled trial in which roflumilast cream 0.15% or vehicle is applied once daily for four weeks to individuals six years of age and older with mild to moderate AD involving ≥3% body surface area. A total of 683 individuals have been enrolled in the study. The primary endpoint is Investigator Global Assessment (IGA) Success, defined as a Validated Investigator Global Assessment – Atopic Dermatitis (vIGA- AD) score of ‘clear’ or ‘almost clear’ plus a 2-grade improvement from baseline at Week 4. Multiple secondary endpoints will also be evaluated, including itch as measured by the Worst Itch-Numerical Rating Scale (WI-NRS) as well as the proportion of subjects who attain at least a 75% reduction in the Eczema Area and Severity Index (EASI-75) at Week 4.

About Atopic Dermatitis
Atopic dermatitis (AD) is the most common type of eczema, affecting approximately 9.6 million children and 16.5 million adults in the United States. 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. The rash can cover significant areas of the body, in some cases half of the body or more. AD typically begins in early childhood and is chronic. It persists into adolescence and even adulthood in some individuals. The rash causes significant pruritus (itching), which can lead to skin damage caused by scratching or rubbing. Since a large percentage of atopic dermatitis patients are young children, safety is a particularly important consideration in treatment selection.

About Roflumilast Cream
Roflumilast cream is a next generation topical PDE4 inhibitor. PDE4 – an established target in dermatology – 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. Roflumilast cream 0.3% (ZORYVE™) is approved by the FDA for the topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older. For atopic dermatitis, roflumilast cream is being evaluated at lower doses: 0.15% for adults and children six years of age and older and 0.05% for children two to five years.

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 including plaque psoriasis, atopic dermatitis, and seborrheic dermatitis. For more information, visit www.arcutis.com or follow Arcutis on LinkedIn, Facebook, 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 children with atopic dermatitis, the potential to use roflumilast cream over a long period of time, or chronically, the potential to use roflumilast cream anywhere on the body, including the face and sensitive areas, timing for anticipated data, the potential sNDA filing

and the potential for roflumilast to advance the standard of care in atopic 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 22, 2022, as amended on March 3, 2022, 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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