Arcutis Presents Late-Breaking Data from the INTEGUMENT Phase 3 Trials in Atopic Dermatitis at American Academy of Dermatology Annual Meeting

March 18, 2023

- New INTEGUMENT-1 and INTEGUMENT-2 data show a rapid and significant reduction in itch as early as 24 hours after the first application of roflumilast cream 0.15%
- Rapid and significant improvements were achieved including individuals reaching a 75% reduction of Eczema Area and Severity Index (EASI-75) as early as Week 1 and in Investigator Global Assessment (IGA) Success as early as Week 2
- In both studies, roflumilast cream improved atopic dermatitis across multiple efficacy endpoints while demonstrating favorable safety and tolerability
- Incidences of adverse events were low, with no adverse event occurring in more than 3.5% of subjects in either arm

WESTLAKE VILLAGE, Calif., March 18, 2023 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), an early commercial-stage company focused on developing meaningful innovations in immuno-dermatology, today presented in a late-breaking clinical trial session at the American Academy of Dermatology (AAD) annual meeting (New Orleans, LA, March 17-21) new data from its INTEGUMENT-1 and INTEGUMENT-2 pivotal Phase 3 studies of roflumilast cream 0.15% in adults and children 6 years and older with mild to moderate atopic dermatitis (AD). Roflumilast cream is a once-daily, steroid-free topical formulation of a highly potent and selective phosphodiesterase-4 (PDE4) inhibitor.

Both studies met the primary endpoint of 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 (INTEGUMENT-1: 32.0% roflumilast cream vs. 15.2% vehicle, P<0.0001; INTEGUMENT-2: 28.9% roflumilast cream vs. 12.0% vehicle, P<0.0001). In addition, rapid and significant improvements in v-IGA success were demonstrated as early as Week 2 (INTEGUMENT-1: 21.2% for roflumilast cream vs. 6.4% for vehicle; P<0.0001; INTEGUMENT-2: 17.7% for roflumilast cream vs 5.3% for vehicle; P< 0.0001).

Over 30% of individuals treated with roflumilast cream in each study achieved Worst Itch Numeric Scale (WI-NRS) Success at Week 4. In addition, a daily improvement in itch was observed in those treated with roflumilast cream with a significant improvement at 24 hours following the first application (P<0.05) as measured by WI-NRS.

“Atopic dermatitis is a chronic skin disease common in both children and adults where pruritus, or itch, is the most reported and most burdensome symptom, and may cause substantially reduced quality of life and sleep disturbances,” said Lawrence F. Eichenfield, MD, Chief of Pediatric and Adolescent Dermatology at Rady Children's Hospital-San Diego, Professor of Dermatology and Pediatrics and Vice-Chair of the Department of Dermatology at UC San Diego School of Medicine, and study investigator. “Importantly, individuals treated with roflumilast cream experienced a significant and rapid improvement in the extent and severity of their atopic dermatitis, adding further to evidence of the potential of roflumilast cream as a treatment option for this disease. Additionally, these pivotal Phase 3 data show that roflumilast cream drove a significant and rapid reduction in itch as early as the first 24 hours, which could be a helpful early indication to children and adults that the treatment is working.”

Roflumilast cream also demonstrated rapid and statistically significant improvements compared to vehicle on key secondary endpoints, with more than 40% of children age 6 and older and adults treated with roflumilast cream achieving a 75% reduction in Eczema Area and Severity Index (EASI-75) at Week 4 compared to vehicle (INTEGUMENT-1: 43.2% vs. 22.0%, P<0.0001; INTEGUMENT-2: 42.0% vs. 19.7%, P<0.0001). Additionally, significant improvements in EASI-75 were observed with roflumilast cream as early as Week 1 in both studies compared to vehicle (INTEGUMENT-1: 14.0% vs. 5.5%, p=0.0006; INTEGUMENT-2: 13.3% vs. 7.8%, p=0.0329). In both studies, approximately 40% of children and adults treated with roflumilast cream achieved a vIGA-AD score of Clear (0) or Almost Clear (1) at Week 4 (INTEGUMENT-1: 41.5% vs. 25.2%, P<0.0001; INTEGUMENT-2: 39% vs. 16.9%, P<0.0001).

“Atopic dermatitis can have a huge impact on the quality of life for those affected, and also be challenging to treat,” said Julie Block, President and CEO, National Eczema Association. “Thankfully, our understanding of atopic dermatitis continues to grow, and the commitment from companies, such as Arcutis, to develop new treatment options aiming to provide people living with this disease a much-needed relief, is most welcome and appreciated.”

“We are pleased to present these data from our pivotal Phase 3 INTEGUMENT program, which demonstrated significant improvements in atopic dermatitis in children and adults across multiple efficacy endpoints,” said Patrick Burnett MD, PhD, FAAD, Chief Medical Officer of Arcutis. “Roflumilast cream was also shown to be safe and well-tolerated, critical considerations for the treatment of atopic dermatitis. We look forward to the continued development of roflumilast cream 0.15% for atopic dermatitis as we prepare to file a supplemental new drug application (sNDA) with the U.S. Food & Drug Administration (FDA) in the second half of this year.”

Roflumilast cream 0.15% was well tolerated. The incidence of Treatment Emergent Adverse Events (TEAEs) was low in both active treatment and vehicle arms, with most TEAEs assessed as mild to moderate in severity, and no adverse event occurring in more than 3.5% of subjects in either arm. The most common TEAEs ≥ 2% in roflumilast-treated patients were headache (INTEGUMENT-1 2.3% vs 1.4%; INTEGUMENT-2 3.5% vs 0.9%), nausea (1.8% vs 0.9%; 2.0% vs 0%), and application site pain (2.1% vs. 0.5%; 0.9% vs. 0.9%). Local tolerability was favorable with more than 90% of those treated with roflumilast cream reporting no or mild sensation across arms in both trials at any timepoint.

About the INTEGUMENT Phase 3 Trials
The “INterventional Trial EvaluatinG roflUMilast cream for the treatmENt of aTopic dermatitis” (INTEGUMENT-1 and INTEGUMENT-2) are two identical Phase 3, parallel group, double blind, vehicle-controlled trials in which roflumilast cream 0.15% or vehicle was applied once daily for four

weeks to individuals 6 years of age and older with mild to moderate AD involving ≥3% body surface area. A total of 1,337 individuals were randomized across both studies. The primary endpoint was IGA Success, defined as vIGA-AD score of 'clear' or 'almost clear' plus a 2-grade improvement from baseline at Week 4. Multiple secondary endpoints were also evaluated, including itch as measured by WI-NRS as well as the proportion of subjects who attained an EASI-75 at Week 4.

After completing INTEGUMENT-1 and INTEGUMENT-2, individuals were 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.

Arcutis is enrolling a third pivotal Phase 3 trial, the "INterventional Trial EvaluatinG roflUMilast cream for the treatmENt of aTopic dermatitis in PEDiatric patients" (INTEGUMENT-PED) to evaluate roflumilast cream 0.05% in children 2 to 5 years of age with mild to moderate AD. The Company plans to report topline data from this study in the second half of 2023.

About 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 AD patients are very 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. 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. Roflumilast cream for atopic dermatitis was evaluated at lower doses: 0.15% for adults and children 6 years of age and older and is being evaluated at 0.05% for children aged 2 to 5 years.

About ZORYVE®
ZORYVE (roflumilast) cream 0.3% is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older.

IMPORTANT SAFETY INFORMATION
The use of ZORYVE is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C).

The most common adverse reactions (≥1%) include diarrhea (3%), headache (2%), insomnia (1%), nausea (1%), application site pain (1%), upper respiratory tract infection (1%), and urinary tract infection (1%).

Please see full Prescribing Information.

About Arcutis
Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a medical dermatology company that champions meaningful innovation to address the urgent needs of individuals living with immune-mediated dermatological diseases and conditions. With a commitment to solving the most persistent patient challenges in dermatology, Arcutis has a growing portfolio that 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 scalp and body psoriasis, atopic dermatitis, seborrheic dermatitis, and alopecia areata. For more information, visit www.arcutis.com or follow Arcutis on LinkedIn, Facebook, and Twitter.

Forward-Looking Statements
Arcutis cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements are based on the Company's current beliefs and expectations. Such forward-looking statements include, among others, statements regarding the potential for roflumilast to be approved for the treatment of adults and children with AD, 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 of INTEGUMENT-PED, the potential sNDA filing and the potential for roflumilast to advance the standard of care in AD and other inflammatory dermatologic conditions. These statements are subject to 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. Risks and uncertainties that may cause our actual results to differ include risks inherent in our business, reimbursement and access to our products, the impact of competition and other important factors discussed in the "Risk Factors" section of our Form 10-K filed with U.S. Securities and Exchange Commission (SEC) on February 28, 2023, as well as any subsequent filings with the SEC. You should not place undue reliance on any forward-looking statements in this press release. 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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