Arcutis Presents New Data on Once-Daily Roflumilast Cream for Plaque Psoriasis from DERMIS Phase 3 Trials at American Academy of Dermatology Annual Meeting

March 25, 2022

- Pooled analysis of DERMIS-1 and DERMIS-2 demonstrated significantly more roflumilast-treated patients achieved Investigator Global Assessment (IGA) success (40%) at week 8 compared to vehicle (7%), consistent with results from the individual studies
- New post hoc analyses showed consistent efficacy regardless of baseline body surface area (BSA) and efficacy in psoriasis patients with knee and/or elbow involvement
- Interim results from an ongoing Phase 3 open-label, long-term study supports the previously established long-term safety profile and demonstrated efficacy of topical roflumilast was maintained through 32 weeks

WESTLAKE VILLAGE, Calif., March 25, 2022 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a late-stage biopharmaceutical company focused on developing meaningful innovations in immunodermatology, today announced new pooled results from the DERMIS Phase 3 trials of roflumilast cream are available in four abstracts at the 2022 American Academy of Dermatology annual meeting, taking place in Boston, MA. Roflumilast is a selective and highly potent phosphodiesterase-4 inhibitor (PDE4) being investigated by Arcutis as a non-steroidal topical treatment for multiple inflammatory skin diseases, including plaque psoriasis.

“These data demonstrate the consistent efficacy of investigational roflumilast cream, in steroid sensitive areas, as well as hard-to-treat areas, such as knees and elbows, and regardless of disease severity. In addition, both patients and healthcare providers reported favorable local tolerability,” said Mark Lebwohl, MD, Dean of Clinical Therapeutics and Professor of Dermatology, Mount Sinai. “These findings are important because the majority of plaque psoriasis patients use topical treatments today. Roflumilast cream, if approved, could provide an important new topical therapy option for the millions of patients with chronic plaque psoriasis.”

Pooled efficacy and safety results from the DERMIS-1 and DERMIS-2 Phase 3 trials showed that at week 8, 40% of patients treated with roflumilast cream achieved IGA success – the achievement of clear or almost clear plus a ≥2 grade improvement from baseline – compared to 7% of patients with vehicle (P<0.0001), and 48% of patients treated with roflumilast cream achieved IGA status of clear or almost clear compared to 10% of patients with vehicle (P<0.0001).

- Of patients with a Worst Itch Number Rating Scale (WI-NRS) of at least 4 on a 10-point scale at baseline, 69% of patients treated with roflumilast cream (n=447) achieved an improvement of four-points or more in their itch (WI-NRS success) compared to 31% of patients treated with vehicle (n=231) at week 8 (P<0.0001).

In both trials, roflumilast cream was generally well-tolerated with a favorable safety and tolerability profile. Rates of application-site adverse events (AEs), treatment-related AEs, and discontinuations due to AEs were low and comparable with vehicle. 1% of patients discontinued the study due to an AE. The most common AEs include diarrhea (3%), headache (2%), insomnia (1%), nausea (1%), upper respiratory tract infection (1%), application-site pain (1%), and urinary tract infection (1%).

New post hoc analyses of pooled results from the DERMIS studies reported in two posters showed:

- As measured by the primary efficacy endpoint of IGA success, roflumilast cream demonstrated consistent efficacy across patients with mild, moderate, or severe psoriasis as defined by baseline body surface area (BSA). At week 8, 47% of patients with baseline BSA involvement >10% achieved IGA success with roflumilast cream, compared to 2% of patients with vehicle (P<0.0001); 37% of patients with baseline BSA of 5-10% achieved IGA success with roflumilast cream (P<0.0001), compared to 9% with vehicle; and 40% of patients with baseline BSA involvement <5% achieved IGA success with roflumilast cream, compared to 7% with vehicle (P<0.0001).
- In patients with psoriasis plaques on their knees and/or elbows (especially challenging areas to treat), roflumilast cream demonstrated clinically meaningful efficacy at 8 weeks, with 49% of these patients achieving IGA of clear or almost clear with roflumilast cream, compared to 8% of patients with vehicle (P<0.0001).

In a separate poster, new interim results from an ongoing 24-week, phase 3 open-label long-term study (DERMIS-OLE) were reported. All efficacy endpoints were maintained throughout the study. Safety and tolerability with long-term exposure to roflumilast cream 0.3% was consistent with what was seen in already completed short-term and long-term studies and further supports long-term use. Roflumilast cream was generally well-tolerated, with ≥96% of patients demonstrating no evidence of irritation at the application sites as assessed by investigators. Adverse events were generally mild or moderate in severity.

“We are pleased to present these new data from our pivotal phase 3 DERMIS program, which resulted in improvements in plaque psoriasis for those with mild, moderate, and severe disease,” said Patrick Burnett, M.D., Ph.D., FAAD, Chief Medical Officer, Arcutis. “Coupled with the favorable tolerability profile, we believe investigational roflumilast cream, if approved, represents an important potential new non-steroidal topical treatment option for chronic use in the treatment of plaque psoriasis.”

In December 2021, the U.S. Food and Drug Administration (FDA) accepted for filing the company’s New Drug Application (NDA) for roflumilast cream

for the treatment of plaque psoriasis in adults and adolescents, with a Prescription Drug User Act target action date of July 29, 2022.

About DERMIS Pivotal Phase 3 Trials
DERMIS-1 and DERMIS-2 (Trials of P**DE**4 inhibition with **R**oflumilast for the **M**anagement of plaque Psorias**IS**" One and Two) were identical Phase 3 randomized, parallel, double-blind, vehicle-controlled, multi-national, multi-center studies to evaluate the safety and efficacy of roflumilast cream 0.3%. Roflumilast met its primary endpoint. DERMIS-OLE is a 24-week, phase 3 open-label safety study that evaluated the long-term safety and efficacy of roflumilast cream 0.3% in adult and pediatric patients with psoriasis and was open to patients who successfully completed a prior roflumilast cream study or were naïve to roflumilast cream.

About Psoriasis
Psoriasis is a common, non-contagious, immune-mediated skin disease that affects more than 8.6 million people in the United States. The majority of patients develop "plaques," or raised, red areas of skin covered with a silver or white layer of dead skin cells. The plaques clinical presentation may have more grayish, purplish, or brownish tones in people with skin of color. Psoriatic plaques are often itchy and sometimes painful, and can appear on any area of the body. Plaques in certain anatomical areas present unique treatment challenges, including the face, elbows and knees, scalp, and intertriginous areas (where two skin areas may touch or rub together.)

About Roflumilast Cream
Roflumilast cream is a topical cream formulation of a highly potent and selective PDE4 inhibitor, roflumilast. Roflumilast has been approved by the FDA for oral treatment to reduce the risk of exacerbations of chronic obstructive pulmonary disease (COPD) since 2011. 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 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 plaque psoriasis, 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 intertriginous areas, and the potential for roflumilast to advance the standard of care in plaque psoriasis 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 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.

Contacts:
Media
Amanda Sheldon, Head of Corporate Communications
asheldon@arcutis.com

Investors
Eric McIntyre, Head of Investor Relations
emcintyre@arcutis.com