New Data from Arcutis' STRATUM Pivotal Phase 3 Trial of Roflumilast Foam 0.3% in Seborrheic Dermatitis Presented at European Academy of Dermatology and Venereology (EADV) Congress

September 9, 2022

- Study met its primary endpoint with 80% of individuals treated with roflumilast foam achieving Investigator Global Assessment (IGA) Success compared to 59% of patients treated with vehicle (P<0.0001)
- More than 60% of patients treated with roflumilast foam achieved an itch response at Week 8, with significant improvements at the 2-and 4-week assessments
- Statistically significant improvements compared to vehicle on all secondary endpoints including scaling and erythema (redness)
- Roflumilast foam was well-tolerated with no evidence of local irritation
- New drug application (NDA) submission anticipated in 1Q of 2023

WESTLAKE VILLAGE, Calif. and MILAN, Italy, Sept. 09, 2022 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), an early-stage commercial company focused on developing meaningful innovations in immuno-dermatology, today announced new data from the STRATUM pivotal Phase 3 trial investigating roflumilast foam as a potential treatment for children ages 9 and above and adults with moderate to severe seborrheic dermatitis were presented orally at the Academy of Dermatology and Venereology (EADV) Congress. Roflumilast foam 0.3% is an investigational once-daily topical foam formulation of a highly potent and selective phosphodiesterase type 4 (PDE4) inhibitor being developed to treat inflammatory dermatoses, particularly in hair-bearing areas of the body such as the scalp.

The study met the primary endpoint with 80.1% of individuals treated with roflumilast foam achieving 'IGA Success' compared to 59.2% of patients treated with vehicle (P<0.0001) at week eight. IGA Success was defined as an IGA score of clear or almost clear plus a ≥2 grade improvement from baseline. Improvement with roflumilast foam was seen early, with roflumilast separating statistically from vehicle on IGA Success at week two, the first timepoint assessed.

"Topical therapies are the standard of care for the treatment of seborrheic dermatitis, but today's options come with limitations, including side effects and the inability to use on both hair- and non-hair- bearing areas of the body," said Dr. Andrew Blauvelt, M.D., M.B.A., lead study author and president of Oregon Medical Research Center. "Roflumilast foam demonstrated strong efficacy across multiple endpoints, including 50% of individuals with seborrheic dermatitis achieving IGA clear at week 8. Local tolerability was also highly favorable as reported by both patient and investigator assessments of irritation, burning, and stinging."

Roflumilast foam also demonstrated statistically significant improvements compared to vehicle on all secondary endpoints in the trial, including itch, scaling, and erythema (redness).

- More than 60% of individuals with a Worst Itch-Numerical Rating Score (WI-NRS) of 4 or higher at baseline treated with roflumilast foam achieved a ≥4-point reduction in itch at Week 8. (63.6% with roflumilast foam vs 42.3% vehicle (P=0.0002))
- More than 50% of individuals treated with roflumilast foam achieved an erythema score of 0 at week 8. (57.9% with roflumilast foam vs 32.7% vehicle (P<0.0001))
- More than 50% of individuals treated with roflumilast foam achieved a scaling score of 0 at week 8. (58.2% with roflumilast foam vs 37.5% vehicle (P=0.0001))

Roflumilast foam was well-tolerated. The incidence of Treatment Emergent Adverse Events (TEAEs) was low and similar between active treatment and vehicle, with most TEAEs assessed as mild to moderate severity. There were no treatment-related Serious Adverse Events (SAEs). Overall, the most common adverse events in the study population (over 1%) included COVID-19, urinary tract infection, nasopharyngitis, and nausea. Over 90% of patients who were randomized to roflumilast foam in the study completed the full eight weeks, and there were few discontinuations due to adverse events (0.7% and 2.0% in the roflumilast foam and vehicle groups, respectively). Roflumilast foam demonstrated favorable local tolerability with no evidence of irritation in >98% of patients as assessed by the investigator and no or mild sensations in reported by >92% across all timepoints and treatment groups.

"We are excited to share these additional data from our STRATUM phase 3 trial which show the potential for roflumilast foam to treat multiple signs and symptoms of seborrheic dermatitis, including itch, redness, and scaling," said Patrick Burnett MD, PhD, FAAD, Chief Medical Officer at Arcutis. "Roflumilast foam continues to demonstrate strong efficacy with a safety and tolerability profile that, if approved, should provide an important new non-steroidal treatment option for chronic use anywhere on the body, including the scalp."

Arcutis plans to submit an NDA for roflumilast foam for the treatment of seborrheic dermatitis to the U.S. Food and Drug Administration (FDA) in the first quarter of 2023.

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 foam 0.3% administered once-daily. A total of 457 subjects ages nine years and older with moderate to severe seborrheic dermatitis were enrolled in the study and were randomized 2:1 roflumilast foam to vehicle. The primary endpoint of

the study was the proportion of subjects achieving IGA Success, defined as an IGA score of clear or almost clear plus a ≥2 grade improvement at week 8.

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
Arcutis is developing topical cream and foam formulations of roflumilast – a highly potent and selective PDE4 inhibitor being investigated as a once-daily, nonsteroidal, topical treatment for multiple dermatologic conditions. 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 foam is a once-daily topical foam formulation of roflumilast which the Company is developing for both seborrheic dermatitis and scalp and body psoriasis.

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 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 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 foam 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, anticipated submission of the NDA 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 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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