# Arcutis Announces Positive Topline Results from STRATUM Pivotal Phase 3 Trial of Roflumilast Foam 0.3% in Seborrheic Dermatitis

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- Study met its primary endpoint with 80.1% of individuals treated with roflumilast foam achieving Investigator Global Assessment (IGA) Success compared to 59.2% of patients treated with vehicle (P<0.0001)
- More than 50% of patients treated with roflumilast foam achieved an IGA score of clear at week eight
- Roflumilast foam was well-tolerated with a favorable safety and tolerability profile
- Data further support the potential of roflumilast foam as a best-in-class, once-daily, non-steroidal topical treatment for seborrheic dermatitis
- New drug application (NDA) submission anticipated in 1H of 2023
- Company to host a conference call today at 8:30 a.m. EDT

WESTLAKE VILLAGE, Calif., June 06, 2022 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a late-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced positive topline results from the STRATUM pivotal Phase 3 trial investigating roflumilast foam as a potential treatment for adolescents and adults with moderate to severe seborrheic dermatitis. Roflumilast foam 0.3%, 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, demonstrated significant improvements based on IGA Success and other endpoints.

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. In addition, more than 50% of patients treated with roflumilast foam achieved an IGA score of clear at week eight. Roflumilast foam also demonstrated statistically significant improvements compared to vehicle on key secondary endpoints, including itch, scaling, and redness (erythema).

"Despite the prevalence and impact on quality of life of seborrheic dermatitis, there remains significant unmet need for new options to treat this condition, with individuals today left to manage their symptoms with multiple treatments and complex application routines," said Dr. Zoe Draelos, study investigator, dermatologist in High Point, North Carolina, and President, Dermatology Consulting Services, PLLC. "As both a trial investigator and a clinician, I am excited by these results because they demonstrate the potential for roflumilast foam to be a well-tolerated, easy-to-use, steroid-free treatment option for adults and adolescents with moderate to severe seborrheic dermatitis."

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).

"We are excited that investigational roflumilast foam demonstrated strong topline results in our pivotal Phase 3 trial, consistent with previously reported data. These results move us one step closer to providing a new treatment option for the millions of people suffering from seborrheic dermatitis," said Patrick Burnett MD, PhD, FAAD, Chief Medical Officer at Arcutis. "We will now prepare an NDA for roflumilast foam for the treatment of seborrheic dermatitis to submit to the U.S. Food and Drug Administration (FDA)."

Arcutis announced in January 2021 that, based on feedback received from the FDA, the Company believes the single STRATUM study, if positive, would be sufficient basis for an NDA for roflumilast foam in dermatitis. Arcutis plans to submit an NDA in the first half of 2023. If roflumilast foam is approved by the FDA, the Company plans to leverage its existing commercial infrastructure to bring the product to market.

Management will host a conference call today at 8:30 a.m. EDT to discuss these results. To access the call, please dial (833) 614-1393 (domestic) or (914) 987-7114 (international) and provide the conference ID# 7384524. A live webcast of the call will also be available on the "Events" section of the Company's Investor website. An archived replay of the webcast will be available on the Arcutis website following the call.

**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 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 Foam**
Roflumilast foam is a once-daily topical foam formulation of roflumilast, a highly potent and selective PDE4 inhibitor, which the Company is developing for both seborrheic dermatitis and scalp and body psoriasis. Roflumilast has been approved by the U.S. FDA for oral treatment to reduce the risk of exacerbations of chronic obstructive pulmonary disease (COPD) since 2011. Arcutis has also submitted an NDA 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.

**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 in plaque psoriasis, one Phase 3 clinical trial now completed in 2022 in seborrheic dermatitis, and two additional Phase 3 clinical data readouts anticipated by the end of the year in atopic dermatitis and scalp and body psoriasis. 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 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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