Arcutis Enrolls Last Patient in Phase 2b Clinical Trial Evaluating ARQ-154 (Topical Roflumilast Foam) as a Potential Treatment for Scalp Psoriasis

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- Roflumilast foam potential “Best in Class” topical PDE4 inhibitor in foam formulation
- Scalp psoriasis affects more than 2.5 million U.S. patients
- Phase 2b topline data anticipated fourth quarter 2020

WESTLAKE VILLAGE, Calif., July 20, 2020 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a late-stage biopharmaceutical company focused on developing and commercializing treatments for unmet needs in immune-mediated dermatological diseases and conditions, or immuno-dermatology, today announced the completion of enrollment of the Phase 2b clinical trial evaluating ARQ-154 (topical roflumilast foam) as a potential treatment for scalp psoriasis. Roflumilast foam is a once-daily topical foam formulation of a highly potent and selective phosphodiesterase type 4 inhibitor (PDE4 inhibitor) that the Company is developing particularly to treat inflammatory dermatoses in hair-bearing areas of the body such as the scalp. The Company now anticipates topline data from this trial in the fourth quarter of 2020.

“An estimated 8.6 million Americans are afflicted with chronic psoriasis, and nearly half of those people have scalp involvement, an area where topical treatment of scalp plaques is complicated by the difficulty of delivering topical drugs under the hair and to the surface of the skin,” said Frank Watanabe, Arcutis’ President and Chief Executive Officer. “We developed roflumilast foam as a convenient, once daily, easy-to-use foam that is safe for chronic use and appropriate for application in hair-bearing areas, such as the scalp, where a cream, lotion, or ointment is not suitable. We believe roflumilast foam may provide a new treatment option for physicians and patients, with the potential to show significant symptomatic improvement similar to high-potency steroids, while at the same time maintaining a low risk of toxicity or side effects.”

Roflumilast foam is a topical foam formulation of a highly potent and selective PDE4 inhibitor (roflumilast). Roflumilast has been approved by the U.S. Food and Drug Administration (FDA) for systemic treatment to reduce the risk of exacerbations of chronic obstructive pulmonary disease (COPD) since 2011. Roflumilast has shown greater potency (25 to 300 fold) than the two other FDA-approved PDE4 inhibitors. 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.

Arcutis believes roflumilast foam has significant potential as a scalp psoriasis treatment. Roflumilast foam is nearly identical to ARQ-151 (topical roflumilast cream), Arcutis' topical cream PDE4 inhibitor that has demonstrated statistically significant improvements of psoriasis symptoms and a favorable tolerability profile in two separate Phase 2 studies. Psoriasis plaques on the scalp are identical to plaques elsewhere on the body, so the roflumilast cream psoriasis results should be highly predictive.

The Phase 2b trial in scalp psoriasis is an 8-week, multi-center, multi-national, double blind, vehicle-controlled, study of the safety and efficacy of topical roflumilast foam 0.3% administered once-daily in approximately 300 adult and adolescent patients with plaque psoriasis that includes plaques on the scalp. The primary endpoint of the trial is achievement of an Investigator Global Assessment score of 'clear' or 'almost clear' plus a 2-grade improvement from baseline on the scalp (S-IGA) at week 8. Multiple secondary endpoints will also be evaluated.

About Scalp Psoriasis
Scalp psoriasis is a manifestation of plaque psoriasis characterized by raised, red areas of skin (“plaques”) covered with a silver or white scale that occurs in the hair-bearing area of the scalp and sometimes extending to the forehead, back of the neck, or behind or inside the ears. Patients with scalp psoriasis commonly have plaques on other areas of the body as well. Nearly half of the estimated 8.6 million Americans with psoriasis have involvement of the scalp. Scalp psoriasis plaques are identical to psoriatic plaques on other areas of the body, however topical treatment of scalp plaques is complicated by the difficulty of delivering topical drugs under the hair and onto the skin. As with psoriatic plaques on other parts of the body, psoriasis on the scalp is often itchy and is sometimes painful. Scalp psoriasis can also be associated with hair loss, likely due to damage to the hair from excessive scratching, rubbing, or combing of the affected area.

About Arcutis - Bioscience, applied to the skin.
Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a late-stage biopharmaceutical company focused on developing and commercializing treatments for unmet needs in immune-mediated dermatological diseases and conditions, or immuno-dermatology. The company is leveraging recent advances in immunology and inflammation to develop differentiated therapies against biologically validated targets to solve persistent treatment challenges in serious diseases of the skin. Arcutis’ robust pipeline includes four novel drug candidates currently in development for a range of inflammatory dermatological conditions. The company’s lead product candidate, topical roflumilast, has the potential to revitalize the standard of care for plaque psoriasis, atopic dermatitis, scalp psoriasis, and seborrheic dermatitis. For more information, visit https://www.arcutis.com or follow the company on LinkedIn and Twitter.

Forward Looking Statements
This press release contains "forward-looking" statements, including, among others, statements regarding roflumilast foam’s potential as a scalp psoriasis treatment; expectations with regard to the timing of clinical data anticipated in the fourth quarter of 2020; and whether roflumilast cream’s Phase 2 results may be predictive of roflumilast foam’s potential clinical outcomes. 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-Q filed with U.S. Securities and Exchange

Commission (SEC) on May 12, 2020, 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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