Arcutis Enrolls Last Patient in Phase 2 Proof of Concept Clinical Trial Evaluating ARQ-154 (Topical Roflumilast Foam) as a Potential Treatment for Seborrheic Dermatitis

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- Roflumilast foam potential “Best in Class” topical PDE4 inhibitor in foam formulation
- Seborrheic dermatitis affects over 6 million U.S. patients
- Phase 2 topline data anticipated early in fourth quarter of 2020
- The Company also announced first patient enrolled in long-term safety study

WESTLAKE VILLAGE, Calif., June 22, 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 it had completed enrollment of its Phase 2 proof of concept clinical trial evaluating roflumilast foam as a potential treatment for seborrheic dermatitis. 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 anticipates topline data from this trial early in the fourth quarter of 2020. In addition, the Company has begun enrollment in a long-term safety study of roflumilast foam in patients with seborrheic dermatitis.

“Seborrheic dermatitis is a common chronic skin disease that primarily occurs on the scalp, face and chest, and is one of the most neglected diseases in dermatology. There are more than six million sufferers in the U.S., many not knowing what it is and thinking it’s just dry skin, and more than 1.5 million who will receive a prescription topical treatment for this condition each year,” said Mark Jackson, MD, Clinical Professor of Medicine (Dermatology) at the University of Louisville. “I believe a significant need exists for novel non-steroidal therapies to treat this disease, particularly for patients who don’t adequately respond to existing treatments. The greatest reward as a physician comes from seeing patients with distressing chronic skin conditions improve with effective treatments. There is a significant need to find better treatment options for patients with seborrheic dermatitis and I look forward to seeing the results from this trial.”

“We are delighted with the strong support from investigators and the speed with which they enrolled this study, both of which underscore the demand for safe and effective new treatments for seborrheic dermatitis,” said Frank Watanabe, Arcutis’ President and Chief Executive Officer. “Roflumilast foam was developed as an easy-to-use once daily foam specifically to treat hair-bearing areas of the body like the scalp, where seborrheic dermatitis occurs, and where a cream, lotion, or ointment is not suitable. A non-steroidal treatment is also preferable for treatment of the mid-face area, especially around the eyes, due to the risks associated with ocular steroid exposure. We believe roflumilast foam has the potential to be the first treatment with a new mechanism of action for seborrheic dermatitis in decades. We expect to announce topline data from this trial by early in the fourth quarter of this year.”

Roflumilast foam is a topical foam formulation of a highly potent and selective PDE4 inhibitor (roflumilast). Roflumilast has been approved by the 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 treatment for seborrheic dermatitis. Roflumilast foam is nearly identical to ARQ-151 (topical roflumilast cream), Arcutis’ investigational topical cream PDE4 inhibitor that has demonstrated symptomatic improvement and a favorable tolerability profile in the Company’s clinical trials in plaque psoriasis, as well as encouraging results in atopic dermatitis.

The Phase 2 proof of concept trial in moderate to severe seborrheic dermatitis is an 8-week, multi-center, multi-national, double blind, vehicle-controlled study of the safety and efficacy of roflumilast foam 0.3% administered once-daily. The primary endpoint of the trial is achievement of an Investigator Global Assessment Scale (IGA) score of 'clear' or 'almost clear' plus a 2-grade improvement from baseline at week 8. This global assessment scale has five severity grades reported from 0-4 and defined as Clear (0), Almost Clear (1), Mild (2), Moderate (3), Severe (4).

The Phase 2 long-term safety study is a multicenter, open-label study of roflumilast foam 0.3% applied once daily in patients with moderate to severe seborrheic dermatitis involving up to 20% total Body Surface Area (BSA). Cohort 1 will include patients who rolled over from the Phase 2 proof-of-concept trial while Cohort 2 will include patients naïve to treatment with topical roflumilast foam. Periodic clinic visits will include assessments for clinical safety, application site reactions, and disease improvement, or progression.

About Seborrheic Dermatitis
Seborrheic dermatitis is a common, chronic or recurrent skin condition that causes red patches covered with large, greasy, flaking yellow-gray scales, and persistent itch. Seborrheic dermatitis occurs most often on the scalp, face (especially on and around the nose, eyebrows, and eyelids), ears, upper chest and back.

About Arcutis - Bioscience, applied to the skin.

Arcutis 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. Arcutis exploits recent innovations in inflammation and immunology to develop potential best-in-class therapies against validated biological targets, leveraging our deep development, formulation and commercialization expertise to bring to market novel dermatology treatments, while maximizing our probability of technical success and financial resources. Arcutis is currently developing four novel compounds, including ARQ-151 (topical roflumilast cream); ARQ-154 (topical roflumilast foam); ARQ-252, and ARQ-255 for multiple indications, including psoriasis, atopic dermatitis, seborrheic dermatitis, and eczema, vitiligo, and alopecia areata. For more information,

please visit www.arcutis.com or follow the Company on LinkedIn.

Forward Looking Statements

This press release contains "forward-looking" statements, including, among others, statements regarding ARQ-154's potential as a seborrheic dermatitis treatment; expectations with regard to the timing of topline data anticipated by early in the fourth quarter of 2020; and whether ARQ-151 Phase 2 results may be predictive of ARQ-154'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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