Arcutis to Advance Topical Roflumilast Foam (ARQ-154) into Phase 3 Development for the Treatment of Seborrheic Dermatitis

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- Phase 3 development to consist of single pivotal trial
- Previously reported data demonstrated that roflumilast foam provided statistically significant improvement and a favorable safety and tolerability profile
- Roflumilast foam potential “Best in Class” topical PDE4 inhibitor
- Seborrheic dermatitis affects 10 million U.S. patients

WESTLAKE VILLAGE, Calif., Jan. 20, 2021 (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 that it will advance its program to develop topical roflumilast foam (ARQ-154) as a treatment for seborrheic dermatitis into Phase 3 following an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA). The Phase 3 program will consist of a single pivotal trial, which the Company anticipates initiating in the second or third quarter of 2021. Roflumilast foam is a once-daily topical foam formulation of roflumilast, a highly potent and selective phosphodiesterase type 4 (PDE4) inhibitor.

“Following our interactions with the FDA, we are delighted to advance topical roflumilast foam into Phase 3 development for the treatment of seborrheic dermatitis, a disease that affects more than 10 million people in the U.S.,” said Patrick Burnett, M.D., Ph.D., FAAD, Arcutis’ Chief Medical Officer. “Results from our Phase 2 clinical trials with once-a-day topical roflumilast foam demonstrated that it provides statistically significant improvements in signs and symptoms of both seborrheic dermatitis and scalp psoriasis compared to a matching vehicle foam, while also being well tolerated. Unlike creams and ointments, roflumilast foam is suitable for use in hair-bearing areas; unlike steroids, it is expected to be suitable for long-term use, including on the face; and unlike shampoos, it is an elegant, quick drying, leave-in foam that doesn’t need to be rinsed out. If successful in the Phase 3 clinical trial and approved for commercialization, roflumilast foam has the potential to become the standard of care in seborrheic dermatitis.”

“Patients are desperate to find new treatment options for seborrheic dermatitis, a common, chronic skin disease affecting the face and scalp that can profoundly affect patients’ appearance and quality of life,” said Matthew Zirwas, M.D., Founder of Bexley Dermatology Research Clinic and an investigator in the trial. “Dermatologists and patients face a real challenge, with current treatment options that are either safe or effective, but rarely both. Based on clinical results to date, topical roflumilast has shown to be safe and effective, rapidly improving both the appearance and the itch, dramatically improving patients’ quality of life. Notably, it comes in a cosmetically-elegant foam that can be used chronically in multiple locations without the burning and stinging associated with other treatment options. If approved, topical roflumilast will be a revolutionary advancement in the treatment of seborrheic dermatitis.”

Roflumilast foam is a once-daily topical foam formulation of a highly potent and selective PDE4 inhibitor that Arcutis is developing particularly to treat inflammatory dermatoses in hair-bearing areas of the body such as the scalp, although it is usable in all areas of the body.

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. In a recently completed Phase 2 study of roflumilast foam in seborrheic dermatitis, roflumilast foam demonstrated statistically significant improvement over the vehicle foam on the trial’s primary endpoint, Investigator Global Assessment (IGA) success, and multiple secondary endpoints including the reduction of itch. Once-daily roflumilast foam also demonstrated a favorable safety and tolerability profile. Additionally, other than a very small change in the formulation, roflumilast foam is identical to roflumilast cream (ARQ-151), Arcutis’ investigational topical cream PDE4 inhibitor, which has demonstrated symptomatic improvement and a favorable tolerability profile in clinical trials in plaque psoriasis, including chronic treatment of psoriasis, as well as encouraging results in atopic dermatitis.

Arcutis is currently conducting a Phase 2 long-term safety study in seborrheic dermatitis. This is a multicenter, open-label study of roflumilast foam 0.3% applied once daily in adolescent and adult patients with seborrheic dermatitis and includes patients who were treated previously in the Phase 2 trial, as well as patients naïve to treatment with topical roflumilast foam. Periodic clinic visits include assessments for clinical safety, application site reactions, and disease improvement, or progression.

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 on the scalp, face (especially on the nose, eyebrows, ears, and eyelids), upper chest, and back.

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 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 the potential of roflumilast foam to address the unmet needs in the topical treatment of seborrheic dermatitis; the potential safety and efficacy of roflumilast foam; and the initiation of a pivotal Phase 3 clinical trial in 2021. 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 November 5, 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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