Arcutis Announces Positive Topline Data from Phase 2 Clinical Trial Evaluating ARQ-154 (Topical Roflumilast Foam) as a Potential Treatment for Seborrheic Dermatitis

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- Roflumilast foam demonstrated statistically significant improvement over the vehicle foam on the trial's primary and multiple secondary endpoints
- Once-daily roflumilast foam demonstrated a favorable safety and tolerability profile
- Roflumilast foam potential "Best in Class" topical PDE4 inhibitor
- Seborrheic dermatitis affects 10 million U.S. patients
- Company to host a conference call today at 8:30 a.m. EST

WESTLAKE VILLAGE, Calif., Sept. 29, 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 positive topline data from its Phase 2 clinical trial evaluating ARQ-154 (topical roflumilast foam) as a potential treatment for seborrheic dermatitis.

Roflumilast foam 0.3% administered once daily for 8 weeks demonstrated statistically significant improvement compared to a matching vehicle foam on key efficacy endpoints in subjects with moderate-to-severe seborrheic dermatitis. On the study's primary endpoint assessed at week 8, roflumilast foam 0.3% achieved an Investigator Global Assessment (IGA) success rate of 73.8% compared to a vehicle rate of 40.9% ($p<0.0001$). IGA success is defined as the achievement of an IGA score of 'clear' or 'almost clear' on a 5-grade scale PLUS at least a two-point change from baseline. The onset of effect was rapid, with ARQ-154 statistically separating from vehicle as early as week 2, the first visit after baseline, on IGA success as well as multiple secondary endpoints. For example, at week 8, 64.6% of subjects treated with roflumilast foam who had a baseline Worst Itch Numeric Rating Scale (WI-NRS) score of 4 achieved an itch reduction of at least 4 points compared to 34.0% of vehicle treated subjects ($p=0.0007$). Other secondary endpoints included overall assessment of erythema and overall assessment of scaling, which also had positive outcomes. Importantly, roflumilast foam was well-tolerated, with rates of application site adverse events, treatment-related adverse events, and discontinuations due to adverse events low and similar to vehicle. Only 2 out of 154 subjects (1.3%) treated with roflumilast foam discontinued the study due to an adverse event, compared to 1 out of 72 subjects (1.4%) treated with the vehicle.

"Seborrheic dermatitis is one of the most common skin conditions dermatologists deal with in adults, right up there with acne, rosacea, psoriasis and eczema. It has an enormous effect on patient's lives because it is so visible and often embarassing, with red, greasy, flaky areas on the face and scalp that are almost impossible to hide. Making it even worse, many of the more than 10 million sufferers in the U.S. may not know what it is, thereby contributing to the problem of under-treatment and inadequate treatment of the disease," said Matthew Zirwas, M.D., founder of the Bexley Dermatology Research Clinic and an investigator in the trial. "Current topical treatments for seborrheic dermatitis have major limitations, either having low efficacy, such as with topical antifungals, topical immunomodulators, low potency steroids and prescription shampoos, or high efficacy but unacceptable side effect profiles, such as with high potency topical steroids. Of the major dermatologic diseases, it has the greatest need for new treatment options. I believe these data demonstrate that once daily roflumilast foam is well-tolerated and effective. In my opinion, if approved, it has the potential to become the new standard of care in seborrheic dermatitis."

"We are delighted with the robust signal for the efficacy of roflumilast foam in this relatively small, study. In this trial, topical roflumilast foam demonstrated meaningful symptomatic improvement, including a reduction in itch, alongside a favorable safety and tolerability profile that supports chronic use," said Patrick Burnett, M.D., Ph.D., FAAD, and Chief Medical Officer of Arcutis. "With once-a-day dosing, roflumilast foam potentially offers the convenience of a single, easy to use product to treat seborrheic dermatitis in all body locations where a patient might be affected. 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 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 Phase 3 clinical trials and approved for commercialization, roflumilast foam will be the first topical drug treatment in decades to offer a novel mechanism of action for the treatment of seborrheic dermatitis, and has the potential to positively affect the symptoms and quality of life of patients who suffer from this distressing chronic skin condition."

Between December 2019 and June 2020, the Phase 2 trial enrolled 226 adult subjects with moderate-to-severe seborrheic dermatitis. This 8-week, multi-center, multi-national, double blind, vehicle-controlled study evaluated the safety and efficacy of roflumilast foam 0.3% administered once-daily to affected areas on the scalp, face, and body. Topline efficacy data, including the primary endpoint, IGA success at week 8, were analyzed using the population of all randomized subjects with the exception of subjects who missed the week 8 IGA assessment specifically due to COVID-19 disruption. Importantly, only two subjects missed the week 8 IGA assessment due to concerns arising from COVID-19, and therefore the Intent-to-Treat (ITT) and modified ITT populations differed by only two subjects. Arcutis expects to present the full results from the trial at a future medical conference.

Management will host a conference call today at 8:30 a.m. EST to discuss these results. To access the call, please dial (833) 614-1393 (domestic) or (914) 987-7114 (international) prior to the scheduled conference call time and provide the conference ID 7378204. A live webcast of the call will be available on the "Investors" section of the company's website, www.arcutis.com. An archived version of the webcast will be available on the Arcutis website after the call.

Roflumilast foam is a once-daily topical foam formulation of a highly potent and selective phosphodiesterase type 4 inhibitor (PDE4 inhibitor) that

Arcutis is developing particularly to treat inflammatory dermatoses in hair-bearing areas of the body such as the scalp.

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 Arcutis' clinical trials in plaque psoriasis, as well as encouraging results in atopic dermatitis. Arcutis completed enrollment in DERMIS-1 and DERMIS-2, the Company's pivotal Phase 3 clinical trials evaluating topical roflumilast cream as a potential topical treatment for plaque psoriasis, and the Company expects to announce topline data in the first quarter of 2021 and to submit a New Drug Application (NDA) submission by the end of 2021. In addition, following its End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA), Arcutis plans to advance its program to develop topical roflumilast cream for the treatment of atopic dermatitis into Phase 3 clinical trials beginning in late 2020 or early 2021.

In addition to this Phase 2 trial, Arcutis is also 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 patients with seborrheic dermatitis and will include patients who were treated previously in the Phase 2 trial, as well as 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 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 ARQ-154's potential as a seborrheic dermatitis treatment; the Company's expectation to present the full results from the seborrheic dermatitis trial at a future medical conference; the Company's plan to announce ARQ-151 topline data for plaque psoriasis in the first quarter of 2021 and to submit a New Drug Application (NDA) submission by the end of 2021; the Company's plan to initiate pivotal Phase 3 clinical trials for ARQ-151 in atopic dermatitis in late 2020 or early 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 August 11, 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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