Arcutis Announces Positive Topline Results from INTEGUMENT-1 Pivotal Phase 3 Trial of Roflumilast Cream in Atopic Dermatitis in Adults and Children Aged Six Years and Older

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- Study met the primary endpoint and all secondary endpoints
- For the primary endpoint, 32.0% of individuals treated with roflumilast cream 0.15% achieved Investigator Global Assessment (IGA) Success compared to 15.2% of individuals treated with vehicle (P<0.0001)
- 43.2% of individuals treated with roflumilast cream 0.15% achieved a 75% reduction in Eczema Area and Severity Index (EASI-75) and 33.6% achieved a clinically meaningful reduction in itch at Week 4
- Roflumilast cream demonstrated a favorable safety and tolerability profile
- Atopic dermatitis affects approximately 26 million adults and children in the U.S.
- Topline results from INTEGUMENT-2 anticipated before end of year

CORRECTION: In a press release issued earlier today under the same headline, please note that the p-value for WI-NRS should have been P<0.01 not P<0.0001.

WESTLAKE VILLAGE, Calif., Nov. 15, 2022 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), an early commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced positive topline results from its INTEGUMENT-1 pivotal Phase 3 trial of roflumilast cream 0.15%, a once-daily, non-steroidal topical phosphodiesterase-4 (PDE4) inhibitor, in adults and children six years and older with mild to moderate atopic dermatitis (AD). The study met its primary endpoint with 32.0% of individuals treated with roflumilast cream 0.15% achieving IGA Success, defined as a validated Investigator Global Assessment – Atopic Dermatitis (vIGA-AD) score of 'clear' or 'almost clear' plus a 2-grade improvement from baseline at Week 4, compared to 15.2% of individuals treated with vehicle (P<0.0001).

"Atopic dermatitis is a chronic and burdensome disease, especially common with children, that has a significant need for rapid-acting topical treatment options outside of corticosteroids, which aren't suitable for long-term care due to local side effects, safety concerns, and potential for rebound or withdrawal," stated Eric Simpson, M.D., M.C.R, F.A.A.D, Professor of Dermatology at Oregon Health & Science University in Portland. "In this pivotal Phase 3 study, roflumilast cream demonstrated strong efficacy, meeting the primary endpoint of IGA success, and was well tolerated. In addition, a significant number of adults and children were able to get to clear or almost clear in only four weeks, pointing to the potential for roflumilast cream to become an important new treatment option for atopic dermatitis."

Roflumilast cream also demonstrated rapid and statistically significant improvements compared to vehicle on all secondary endpoints, including 43.2% of individuals treated with roflumilast cream 0.15% achieving a 75% reduction in Eczema Area and Severity Index (EASI-75) at Week 4 compared to 22.0% treated with vehicle (P<0.0001).

In addition, the study measured reduction in itch in individuals 12 years of age and older, with 33.6% of individuals treated with roflumilast cream achieving a four-point reduction in Worst Itch Numeric Scale (WI-NRS) at Week 4 (vs. 20.7% for vehicle-treated subjects, [P<0.01]).

Atopic dermatitis is the most common type of eczema, affecting approximately 9.6 million children and 16.5 million adults in the United States. Topical therapies are an important treatment option for the majority of individuals who use pharmaceuticals to treat their disease.

"Today's positive data from INTEGUMENT-1 adds to the growing body of evidence for the overall potential of roflumilast cream as an effective and well-tolerated treatment in atopic dermatitis," said Patrick Burnett, M.D., Ph.D., F.A.A.D., Chief Medical Officer of Arcutis. "Roflumilast cream is a next-generation PDE4 inhibitor that was well tolerated and safe in this trial, providing rapid and robust clearance of the disease as well as reduction in itch. We are encouraged by these findings and look forward to reporting out the second INTEGUMENT study before the end of the year."

Roflumilast cream 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, adverse events were uncommon, with no adverse event occurring in more than 2.5% of subjects in either arm. The most frequent adverse events (>1%) included headache, nausea, application site pain, nasopharyngitis, COVID-19, diarrhea, and vomiting. Over 93% of patients who were randomized to roflumilast cream in the study completed the full four weeks, and there were few discontinuations due to adverse events (1.4% and 1.4% in the roflumilast cream and vehicle groups, respectively).

The Company is anticipating topline results from the identically designed pivotal Phase 3 trial INTEGUMENT-2 by the end of 2022, and is planning to host an investor call to discuss both trials at that time. If successful, the Company intends to submit a supplemental New Drug Application (sNDA) in 2023 for roflumilast cream 0.15% for the treatment of mild to moderate AD in individuals aged six years and older.

About INTEGUMENT-1
The "INterventional Trial EvaluatinG roflUMilast cream for the treatmENt of aTopic dermatitis" 1 (INTEGUMENT-1) is a Phase 3, parallel group, double blind, vehicle-controlled trial in which roflumilast cream 0.15% or vehicle is applied once daily for four weeks to individuals six years of age and older with mild to moderate AD involving ≥3% body surface area. A total of 654 individuals were enrolled in the study. The primary endpoint was Investigator Global Assessment (IGA) Success, defined as a validated Investigator Global Assessment – Atopic Dermatitis (vIGA-AD) score of 'clear' or 'almost clear' plus a 2-grade improvement from baseline at Week 4. Multiple secondary endpoints were also evaluated, including itch as measured by the Worst Itch-Numerical Rating Scale (WI-NRS) as well as the proportion of subjects who attained at least a 75% reduction in the Eczema Area and Severity Index (EASI-75) at Week 4.

After completing INTEGUMENT-1 and INTEGUMENT-2, individuals were eligible to enroll in an open label extension study (INTEGUMENT-OLE) evaluating treatment with once daily roflumilast cream 0.15% for up to 12 months.

Arcutis is enrolling a third pivotal Phase 3 trial, the "INterventional Trial EvaluatinG roflUMilast cream for the treatmENt of aTopic dermatitis in PEDiatric patients" (INTEGUMENT-PED) to evaluate roflumilast cream 0.05% in children two to five years of age with mild to moderate AD. The Company plans to report topline data from this study in 2023.

About Atopic Dermatitis
Atopic dermatitis (AD) is the most common type of eczema, affecting approximately 9.6 million children and 16.5 million adults in the U.S. AD is characterized by a defect in the skin barrier, which allows allergens and other irritants to enter the skin, leading to an immune reaction and inflammation. This reaction produces a red, itchy rash, most frequently occurring on the face, arms, and legs. The rash can cover significant areas of the body, in some cases half of the body or more. AD typically begins in early childhood and is chronic. It persists into adolescence and even adulthood in some individuals. The rash causes significant pruritus (itching), which can lead to skin damage caused by scratching or rubbing. Since a large percentage of atopic dermatitis patients are very young children, safety is a particularly important consideration in treatment selection.

About Roflumilast Cream
Roflumilast cream is a next generation topical PDE4 inhibitor. PDE4 – an established target in dermatology – 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. For atopic dermatitis, roflumilast cream is being evaluated at lower doses: 0.15% for adults and children six years of age and older and 0.05% for children two to five years.

Roflumilast cream 0.3% (ZORYVE™) is approved by the FDA for the topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older.

About Arcutis
Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a medical dermatology company that champions meaningful innovation to address the urgent needs of individuals 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 including scalp psoriasis, atopic dermatitis, and seborrheic dermatitis. For more information, visit www.arcutis.com or follow Arcutis on LinkedIn, Facebook, and Twitter.

Forward-Looking Statements
Arcutis cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements are based on the Company's current beliefs and expectations. Such forward-looking statements include, among others, statements regarding the potential for roflumilast to be approved for the treatment of adults and children with atopic dermatitis, the potential to use roflumilast cream over a long period of time, or chronically, the potential to use roflumilast cream anywhere on the body, including the face and sensitive areas, timing for anticipated data of INTEGUMENT-2 and INTEGUMENT-PED, the potential sNDA filing and the potential for roflumilast to advance the standard of care in atopic dermatitis and other inflammatory dermatologic conditions. These statements are subject to 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. Risks and uncertainties that may cause our actual results to differ include risks inherent in our business, reimbursement and access to our products, the impact of competition and other important factors discussed in the "Risk Factors" section of our Form 10-K filed with U.S. Securities and Exchange Commission (SEC) on February 22, 2022, as amended, as well as any subsequent filings with the SEC. You should not place undue reliance on any forward-looking statements in this press release. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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