Arcutis Completes Enrollment in INTEGUMENT-PED Pivotal Phase 3 Trial of Roflumilast Cream 0.05% for the Treatment of Atopic Dermatitis in Children Ages 2 to 5

May 2, 2023

- A total of 652 children, ages 2 to 5, were enrolled in the study
- Topline data expected in the third quarter
- Atopic dermatitis (AD) affects approximately 26 million adults and children in the United States

WESTLAKE VILLAGE, Calif., May 02, 2023 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), an early commercial-stage biopharmaceutical company focused on developing meaningful innovations in immune-dermatology, today announced the enrollment of the last subject in the INTEGUMENT-PED Pivotal Phase 3 trial evaluating roflumilast cream 0.05% for the treatment of mild to moderate AD in children ages 2 to 5. Roflumilast cream is a once-daily topical formulation of roflumilast, a highly potent and selective phosphodiesterase type 4 inhibitor (PDE4), which the Company is evaluating in two doses for AD: 0.15% for adults and children 6 years of age and older, and 0.05% for children aged 2 to 5 years. Arcutis previously reported positive topline data in similarly designed Pivotal Phase 3 trials of roflumilast cream 0.15% in ages 6 and above.

AD 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.

“Topical steroids are the first-line of treatment for AD in children, and there are few treatment options available for chronic use. It was critical for Arcutis that we developed and studied the effectiveness and safety of roflumilast cream in children as young as age 2 because of the tremendous burden AD can represent, including lack of sleep and persistent itch,” said Patrick Burnett, MD, PhD, FAAD, Chief Medical Officer at Arcutis. “Roflumilast cream is a once-daily, steroid free treatment that was formulated to be a non-greasy, moisturizing cream that absorbs quickly. In addition, roflumilast cream does not include sensitizing excipients or irritants such as propylene glycol.”

The Company plans to report topline data for the INTEGUMENT-PED trial in the third quarter 2023. If successful, the Company expects these data to be sufficient basis for a separate supplemental new drug application (sNDA) submission after the approval of roflumilast cream 0.15% in AD for ages 6 and above. Arcutis plans to submit the new drug application (NDA) for roflumilast cream 0.15% for adults and children age 6 and older in the second half of 2023.

About INTEGUMENT-PED
The “INterventional Trial Evaluating roflUMilast cream for the treatmENt of aTopic dermatitis in PEDiatric patients” (INTEGUMENT-PED) is a Phase 3, parallel group, double blind, vehicle-controlled trial in which roflumilast cream 0.05% or vehicle is applied once-daily for four weeks to children 2 to 5 years of age with mild to moderate AD. A total of 652 individuals have been enrolled in the study. The primary endpoint is 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 will also be evaluated, including itch as measured by the Worst Itch-Numerical Rating Scale (WI-NRS) as well as the proportion of subjects who attain at least a 75% reduction in the Eczema Area and Severity Index (EASI-75) at Week 4.

About Atopic Dermatitis
AD is the most common type of eczema, affecting approximately 9.6 million children and 16.5 million adults in the United States. 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 AD 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. 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. Roflumilast cream for AD was evaluated at lower doses: 0.15% for adults and children 6 years of age and older and is being evaluated at 0.05% for children aged 2 to 5 years.

About ZORYVE
ZORYVE (roflumilast) cream 0.3% is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older.

IMPORTANT SAFETY INFORMATION
The use of ZORYVE is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C).

The most common adverse reactions (≥1%) include diarrhea (3%), headache (2%), insomnia (1%), nausea (1%), application site pain (1%), upper respiratory tract infection (1%), and urinary tract infection (1%).

Please see full Prescribing Information.

About Arcutis

Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is an early commercial-stage 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 has a growing portfolio that 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 and body psoriasis, atopic dermatitis, seborrheic dermatitis, and alopecia areata. 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 AD, 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-PED, the potential sNDA filing and the potential for roflumilast to advance the standard of care in AD 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 28, 2023, 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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