Majority of Individuals with Atopic Dermatitis Improved with Arcutis' Roflumilast Cream 0.15% According to New Data from Phase 3 Program

January 14, 2024

- Individual patient response data highlight 91.5% of individuals treated with roflumilast cream had a measurable improvement in Eczema Area and Severity Index (EASI) in just 4 weeks
- 85% achieved measurable improvement by Week 1 (the earliest timepoint measured)
- Data presented at the 2024 Winter Clinical Dermatology Conference - Hawaii

WESTLAKE VILLAGE, Calif., Jan. 14, 2024 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced new individual patient response data showing the vast majority of individuals (91.5%) treated with investigational roflumilast cream 0.15% had a measurable improvement in Eczema Area and Severity Index (EASI) in 4 weeks. New pooled analyses from two pivotal Phase 3 studies (INTEGUMENT-1 and INTEGUMENT-2) were presented at the 2024 Winter Clinical Dermatology Conference – Hawaii held January 12-17, 2024, in Honolulu, HI. Roflumilast cream 0.15% is a once-daily, steroid-free cream being investigated for adults and children 6 years of age and older with atopic dermatitis.

At Week 4, a statistically significant greater percentage of patients achieved a 50% reduction in EASI scores (EASI-50), with 69.2% of patients treated with roflumilast cream compared to 44.4% of those treated with vehicle ($p<0.0001$) based on observed data. At the same 4-week endpoint, a 75% reduction in EASI scores (EASI-75) was achieved in 44.5% of roflumilast-treated patients compared to 21.2% of vehicle-treated patients ($p<0.0001$). Importantly, EASI-90 was observed in 22.4% of patients treated with roflumilast cream compared to 8.6% of vehicle-treated patients ($p<0.0001$) and a 100% reduction (EASI-100) was observed in 9.8% of patients treated with roflumilast cream compared to 4.8% of vehicle-treated patients ($p<0.002$).

"These individual patient response data can give confidence to clinicians that roflumilast cream can provide predictable and effective improvement of atopic dermatitis, with 70% of adults and children achieving EASI-50 and nearly one in four achieving 90% or greater improvement in eczema area and severity. If approved, the consistent efficacy with daily application over a four week period combined with a tolerability and safety profile without limitations on body regions or duration treated will make this a great addition for management of pediatric and adult atopic dermatitis," said Lawrence Eichenfield, MD, chief of pediatric and adolescent dermatology at Rady Children's Hospital-San Diego, professor of dermatology and pediatrics and vice-chair of the department of dermatology at UC San Diego School of Medicine, and study investigator.

"These data demonstrate the rapid and reliable efficacy of roflumilast cream in atopic dermatitis with the majority of individuals achieving measurable improvement in EASI in as little as one week," said Patrick Burnett, MD, PhD, FAAD, chief medical officer of Arcutis. "We are pleased to be able to share these individual response data with the wider dermatology community and develop a better understanding about the consistent clinical response to roflumilast cream for patients with atopic dermatitis."

Roflumilast cream 0.15% safety and tolerability data were comparable with vehicle, with low rates of application site adverse events (AEs), treatment-related AEs, and discontinuations due to AEs. The most common adverse reactions included headache (2.9%), nausea (1.9%), application site pain (1.5%), diarrhea (1.5%), and vomiting (1.5%).

INTEGUMENT-1 and INTEGUMENT-2 (The INterventional Trial EvaluatinG roflUMilast cream for the treatmENt of aTopic dermatitis) were two identical Phase 3, parallel group, double blind, vehicle-controlled trials evaluating the safety and efficacy of roflumilast cream 0.15% in AD.

Poster Details
Roflumilast Cream 0.15% in Patients With Atopic Dermatitis: Individual Patient EASI Responses: Pooled INTEGUMENT 1 and INTEGUMENT 2 Phase 3 Trials
Simpson, E et al.

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. It 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, and in some cases covers half of the body or more.

About Roflumilast Cream
Roflumilast cream is a next generation topical phosphodiesterase-4 (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 Food and Drug Administration (FDA) for the topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older. Investigational roflumilast cream was evaluated at lower doses for atopic dermatitis: 0.15% for adults and children 6 years of age and older and 0.05% for children aged 2 to 5 years. Roflumilast cream 0.15% is under review at the FDA for the treatment of adults and children 6 years of age and older with a Prescription Drug User Fee Act (PDUFA) target action date of July 07, 2024.

Roflumilast cream is uniquely formulated as a non-greasy emollient cream that absorbs quickly and does not disrupt the skin barrier. In addition, roflumilast cream does not include sensitizing excipients or irritants, such as propylene glycol, polyethylene glycol, isopropyl alcohol, ethanol, or fragrances.

About ZORYVE® Cream
ZORYVE (roflumilast) cream 0.3% is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and

older.

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

The most common adverse reactions (≥1%) include diarrhea (3.1%), headache (2.4%), insomnia (1.4%), nausea (1.2%), application site pain (1.0%), upper respiratory tract infection (1.0%), and urinary tract infection (1.0%).

Please see full **Prescribing Information**.

About Arcutis
Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a 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 including two FDA approved products that harness 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, and alopecia areata. For more information, visit www.arcutis.com or follow Arcutis on LinkedIn, Facebook, and X.

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, but are not limited to, statements regarding the potential and timing for roflumilast cream to be approved by the FDA 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, and the potential for roflumilast cream to advance the standard of care in atopic dermatitis and other inflammatory dermatological 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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