FDA Accepts Arcutis' Supplemental New Drug Application for Roflumilast Cream 0.15% for the Treatment of Atopic Dermatitis in Adults and Children Down to Age 6

November 29, 2023

- FDA has set a PDUFA target action date of July 07, 2024
- Atopic dermatitis affects approximately 16.5 million adults and 9.6 million children in the United States
- sNDA supported by positive efficacy and safety data from the pivotal Phase 3 INTEGUMENT-1 and INTEGUMENT-2 trials

WESTLAKE VILLAGE, Calif., Nov. 29, 2023 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), an early commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced the U.S. Food and Drug Administration (FDA) has accepted its supplemental new drug application (sNDA) for roflumilast cream 0.15% for the treatment of atopic dermatitis (AD) in adults and children down to age 6. Roflumilast cream is a once-daily, steroid-free, phosphodiesterase-4 (PDE4) inhibitor. The FDA assigned the application a Prescription Drug User Fee Act (PDUFA) target action date of July 07, 2024.

"Atopic dermatitis is a chronic and recurring inflammatory skin condition that requires therapy that is effective, tolerable, and suitable for long-term use by both adults and children. Due to its waxing and waning nature, long-term disease control is ideal for the patient versus cyclical treatment, which consists of starting and stopping treatment when skin is controlled and when it is not," 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. "In clinical trials, roflumilast cream demonstrated rapid and sustained improvement in the signs and symptoms of disease, as well as long-term proactive disease control with twice weekly maintenance dosing. With this profile, patients will not need to make tradeoffs between long-term safety, efficacy, and tolerability. Roflumilast cream if approved, has the potential to simplify the approach to disease control for children and adults."

"With this filing acceptance, we are one step closer to potentially providing a new topical option for the millions of Americans living with atopic dermatitis. Given the prevalence of this disease in both children and adults, as well as the need for better long-term management, we believe once-daily, steroid-free roflumilast cream has the potential to become the new standard of care in atopic dermatitis," said Frank Watanabe, president and chief executive officer at Arcutis. "We look forward to working closely with the FDA during the review process as part of our ongoing efforts to develop topical roflumilast for the treatment of immune-mediated skin diseases."

The sNDA is supported by positive results from three Phase 3 programs as well as a Phase 2 dose ranging study, and two Phase 1 pharmacokinetic studies. 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. Roflumilast met its primary endpoint with a validated Investigator Global Assessment – Atopic Dermatitis (vIGA-AD) Success rate of 32.0% compared to a vehicle rate of 15.2% (P<0.0001), and 28.9% compared to a vehicle rate of 12.0% (P<0.0001) at Week 4, in INTEGUMENT-1 and -2, respectively.

Over 30% of individuals treated with roflumilast cream in each study achieved Worst Itch-Numeric Rating Scale (WI-NRS) Success at Week 4, with rapid and significant improvements observed as early as 24 hours following the first application.

In addition, more than 40% of children and adults treated with roflumilast cream achieved a 75% reduction in Eczema Area and Severity Index (EASI-75) at Week 4 compared to vehicle (INTEGUMENT-1: 43.2% vs. 22.0%, P<0.0001; INTEGUMENT-2: 42.0% vs. 19.7%, P<0.0001) with significant results observed as early as Week 1 in both studies (nominal P=0.0006; nominal P=0.0329).

Roflumilast cream 0.15% was well tolerated. The incidence of Treatment Emergent Adverse Events (TEAEs) was low in both active treatment and vehicle arms, with most TEAEs assessed as mild to moderate in severity. There were no adverse reactions in the combined Phase 3 pivotal trials that occurred in more than 2.9% of subjects in either arm. The most common adverse reactions included headache (2.9%), nausea (1.9%), application site pain (1.5%), diarrhea (1.5%), and vomiting (1.5%).

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 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 6 years of age and older. Roflumilast cream for AD was evaluated at lower doses than the approved psoriasis dose: 0.15% for adults and children 6 years of age and older and 0.05% for children aged 2 to 5 years.

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 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 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, among others, statements regarding the potential for roflumilast and regulatory timing for FDA approval based on the PDUFA 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, 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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