Arcutis Announces New Long-Term Data of Roflumilast Cream 0.15% for the Treatment of Mild to Moderate Atopic Dermatitis (AD) in Adults and Children Down to Age Six Presented at Revolutionizing Alopecia Areata, Vitiligo, and Eczema Conference

June 10, 2024

- Investigational roflumilast cream 0.15% showed continued improvements in the signs and symptoms of AD, including itch, through 56 weeks of treatment
- 66.2% of participants treated with once-daily roflumilast cream 0.15% in both the 4-week parent study and the 52-week open label extension achieved a 75% improvement in Eczema Area and Severity Index (EASI-75) at Week 56
- For participants who achieved disease clearance and switched to proactive twice weekly application of roflumilast cream, the median duration of disease control was 281 days
- Once-daily, roflumilast cream 0.15% was well tolerated, with no new safety signals observed for up to 56 weeks of treatment

CHICAGO and WESTLAKE VILLAGE, Calif., June 10, 2024 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced new results from the INTEGUMENT-OLE long-term open-label study of investigational once-daily roflumilast cream 0.15% in adults and children ages 6 years and older with AD presented at the Revolutionizing Alopecia Areata, Vitiligo, and Eczema Conference. In the study, roflumilast cream was well-tolerated with no new safety signals observed over 56 weeks of treatment. Efficacy was not only maintained but improved over time, with 56.6% of participants who continued use of roflumilast cream from the initial trial and 53.8% of participants who switched to roflumilast cream 0.15% from vehicle after the initial trial achieving validated Investigator Global Assessment-Atopic Dermatitis (vIGA-AD) success, defined as vIGA-AD value of 0 or 1 plus a 2-grade improvement from baseline, at Week 56.

Starting at Week 4 of INTEGUMENT-OLE, participants who achieved a vIGA-AD score of clear (0), switched to proactive twice-weekly application (130 participants; 19.8% of study population). For these participants, after their first switch to twice-weekly application, the median duration of disease control (maintaining vIGA-AD of 0 or 1 with adequate control of signs and symptoms on the twice-weekly schedule application) was 281 days (95% CI: 147, not evaluable). In addition, 57.7% of these participants maintained disease control on the twice weekly schedule through their final study day.

"AD is a chronic, burdensome skin condition that requires clinicians and patients to seek a treatment option that can be safely and effectively used long-term for an adult or child," said Melinda Gooderham, MSc, MD, FRCPC, medical director, SKiN Centre for Dermatology, investigator with Probity Medical Research, and study presenter. "Importantly, investigational roflumilast cream 0.15% showed continued improvement through the course of the study, demonstrating that once approved, roflumilast cream may be an effective long-term, steroid-free treatment option that can be used for proactive flare-free disease control. These results also reinforce the durable efficacy and tolerability of roflumilast cream in AD, which could translate to improved treatment adherence."

"Adults and children with AD deserve treatment standards that focus on maintaining long-term disease control, rather than reactively managing flares. This novel pivotal study design evaluated proactive twice-weekly application with a targeted topical treatment, and demonstrated that after achieving disease clearance, patients can maintain disease control for at least 281 days," said Emma Guttmann-Yassky, MD, PhD, Waldman Professor of Dermatology and Immunology, Icahn School of Medicine at Mount Sinai, chair of the Kimberly and Eric J. Waldman Department of Dermatology, Mount Sinai Health System, and director of the Laboratory for Inflammatory Skin Diseases at Mount Sinai. "These results provide support for shifting the paradigm from reactively chasing flares to long-term flare-free disease management." Dr. Guttmann-Yassky is a paid consultant with Arcutis Biotherapeutics.

Additional results presented include:

- 66.2% and 64.6% of participants who rolled over from the roflumilast cream arm in INTEGUMENT-1 or -2 or switched to once-daily roflumilast cream 0.15% from the vehicle arm demonstrated a 75% improvement from baseline in EASI-75 after 56 weeks, respectively.
- 56.9% and 50.0% of participants who participated and switched to once-daily roflumilast cream 0.15% treatment achieved a significant reduction (≥24-point) in itch based on daily Worst Itch Numeric Rating Scale (WI-NRS) among patients aged ≥12 years with baseline WI-NRS ≥4 at Week 56, respectively.

These long-term study results provide further support for the safety and tolerability profile of roflumilast cream already seen in the pivotal INTEGUMENT-1 and INTEGUMENT-2 clinical trials, with no new safety signals observed up to 56 weeks. Overall incidence of adverse events was low, with most being mild to moderate in severity. The most frequently reported adverse events (≥2%) included: COVID-19, upper respiratory tract infection, nasopharyngitis, and headache. Overall, only 3.0% of trial participants discontinued the study due to adverse events.

"Investigational roflumilast cream 0.15% is designed to provide clinicians and individuals with AD with a long-term treatment option that is formulated free of known ingredients or allergens that may disrupt and compromise skin barrier integrity," said Patrick Burnett, MD, PhD, FAAD, chief medical officer at Arcutis. “Based on these positive results, individuals can expect long-term efficacy and improvement in the signs and symptoms of AD, including itch, from roflumilast cream. If approved, we believe that roflumilast cream offers patients with AD an important steroid-free topical option that can provide lasting symptom relief which is maintained over time.”
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 INTEGUMENT-OLE
The “Interventional Trial Evaluating roflumilast cream for the treatment of Atopic dermatitis Open Label Extension” (INTEGUMENT-OLE) was a Phase 3, multicenter, open-label extension study of the long-term safety of roflumilast cream 0.15% in adults and children ages 6 years and older with AD and roflumilast cream 0.05% in children ages 2 to 5 years. Individuals completing the INTEGUMENT-1 or INTEGUMENT-2 Phase 3 trials were eligible to enroll (n=658) for either 24 or 52 weeks. Reported here are data from adults and children down to age 6.

The study evaluated monotherapy with roflumilast cream with no rescue treatment permitted. Beginning at Week 4 of INTEGUMENT-OLE, any participant who achieved vIGA-AD of ‘0-Clear’ switched to twice-weekly proactive treatment. Participants were able to continue twice-weekly proactive dosing, as long as vIGA-AD remained either ‘0-Clear’ or ‘1-Almost Clear’. Participants resumed once-daily dosing if vIGA-AD reached ≥2-Mild and could also resume once-daily dosing if signs/symptoms of AD were not adequately controlled with proactive therapy despite remaining at vIGA-AD of ‘1-Almost Clear’.

The primary objective of the study was to assess the long-term safety of roflumilast cream after either 24 or 52 weeks of treatment. Secondary endpoints include vIGA-AD score of 0 or 1 at each assessment, vIGA-AD success, WI-NRS score over time, and EASI score over time. The assessment of IGA Success and EASI-75 response, as reported here, references baseline of INTEGUMENT-1 and -2.

About Atopic Dermatitis
The most common type of eczema, AD affects approximately 9.6 million children and 16.5 million adults in the United States. AD is a chronic, relapsing inflammatory skin disease that is genetically pre-disposed and presents across the lifespan. The disease appears as a red, intensely itchy rash that can occur anywhere on the body and may present differently in children and adults. AD presentation can rapidly fluctuate and vary based on geographic location and environment.

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 AD: 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. Arcutis intends to submit a supplemental new drug application (sNDA) for roflumilast cream 0.05% in ages 2 to 5 following the potential approval of roflumilast cream 0.15%.

About ZORYVE Cream
ZORYVE (roflumilast) cream 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, AD, and alopecia areata. For more information, visit www.arcutis.com or follow Arcutis on LinkedIn, Facebook, Instagram 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 of roflumilast cream to simplify disease management for care of AD; the potential of real-world use results of roflumilast cream, as well as the potential approval of roflumilast cream for AD. 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 27, 2024, 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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