Arcutis Presents New Phase 2 Long-Term Data Showing Sustained Efficacy and Clearance for a Median of 10 Months with Roflumilast Cream in Adults with Chronic Plaque Psoriasis

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- *During the open label trial, 57.1% of roflumilast-treated participants achieved Investigator Global Assessment (IGA) of clear or almost clear at any time in study; the median duration of clear or almost clear was 10 months (40.1 weeks)*
- *Efficacy was consistent over time across all endpoints, and no lessening of response (no tachyphylaxis) from roflumilast cream was observed*
- *Long-term IGA success and Intertriginous-Investigator Global Assessment (I-IGA) success results are consistent with results from the DERMIS-1 and DERMIS-2 Phase 3 clinical trials*
- *Roflumilast cream was very well-tolerated, with low rates of discontinuations due to either adverse events or lack of efficacy*

WESTLAKE VILLAGE, Calif., Jan. 14, 2023 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), an early commercial-stage company focused on developing meaningful innovations in immuno-dermatology, today announced new safety and efficacy durability data from its open label Phase 2 long-term safety study evaluating once-daily roflumilast cream (0.3%) in adults with chronic plaque psoriasis. Roflumilast cream 0.3% (ZORYVE®) is a once-daily steroid free topical phosphodiesterase-4 (PDE4) inhibitor approved by the US Food and Drug Administration in July 2022.

The study, which was presented at the Winter Clinical dermatology meeting, showed that during the trial, 57.1% (n=185) of roflumilast cream-treated patients achieved an Investigator Global Assessment (IGA) score of clear or almost clear (IGA 0/1) at any time in study, and these participants had a median duration of IGA of clear or almost clear of more than 10 months (40.1 weeks). Additionally, the percentages of participants achieving IGA success (defined as clear/almost clear plus 2-grade improvement from baseline) and an IGA of clear or almost clear were maintained over the course of the 52 weeks, and were consistent with the DERMIS trials. Roflumilast cream was safe and very well tolerated, with the majority of adverse events (AEs) mild-to-moderate in severity.

"We know roflumilast cream is a safe and effective treatment option for those with plaque psoriasis, but what makes these data so exciting is that it shows roflumilast cream continues to be effective over a long period of time with no signs of tachyphylaxis, which is an important consideration when choosing a treatment option for a chronic skin condition," said Mark Lebwohl, MD, FAAD, principal investigator and Dean for Clinical Therapeutics and Chairman Emeritus of the Kimberly and Eric J. Waldman Department of Dermatology at the Icahn School of Medicine at Mount Sinai; and a paid consultant and investigator for Arcutis. "Importantly, the trial design allowed patients to use roflumilast cream 0.3% similar to how it is expected to be used in the real world, adjusting application for clearance of lesions across the body while maintaining results."

In the multicenter, open-label, single-arm, long-term Phase 2 safety trial, two cohorts of participants were enrolled (n=332). Cohort-1 participants (n=230) were those who completed the Phase 2b trial through Week 12 (roflumilast 0.3% treated, roflumilast 0.15% treated, and vehicle treated), whereas Cohort-2 participants (n=102) were newly enrolled (treatment-naïve at baseline).

Additional key findings following 52 weeks of treatment with roflumilast cream 0.3% include:

- IGA success was achieved by 35.3% of participants previously treated with roflumilast cream and 37.5% of roflumilast-naïve participants. IGA success was defined as clear/almost clear plus 2-grade improvement from baseline
- 42% of participants previously treated with roflumilast cream and 47.5% of roflumilast-naïve participants achieved an IGA score of clear or almost clear (IGA 0/1) at Week 52
- 66.7% of participants in Cohort-2[1] achieved Intertriginous-IGA (I-IGA) success, defined as clear or almost clear plus 2-grade improvement from baseline
- No tachyphylaxis occurred, and efficacy was consistent over time among participants who achieved an IGA of clear or almost clear.

"These new findings are significant, as the data build upon previous results from our clinical trial programs and our FDA approval, demonstrating durable safety and long-term efficacy of roflumilast cream for those with psoriasis, including people with the condition in intertriginous areas," said Patrick Burnett, MD, PhD, FAAD, Chief Medical Officer at Arcutis. "This growing body of evidence continues to reinforce that ZORYVE should be a preferred treatment option for those with this condition - especially in areas of the body that are traditionally difficult to treat."

Safety data showed rates of discontinuations due to AEs were low, and ≥97% of patients had no evidence of irritation per investigator local tolerability assessment at each visit. The most common AEs over the course of the trial (>2%) were upper respiratory tract infection/viral URTI (6.6%), nasopharyngitis (3.6%), urinary tract infection (3.3%), and sinusitis (2.4%).

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[1]Cohort 1 not shown because I-IGA added as study amendment and numbers of patients evaluated are very small at each timepoint.

About ZORYVE (roflumilast) Cream 0.3%
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, but are not limited to, statements regarding the potential for ZORYVE to simplify disease management for care of plaque psoriasis; the potential of real-world and long-term use results of roflumilast cream, as well as the commercial launch of ZORYVE in plaque psoriasis. 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 the 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.

Contacts:
Media
Amanda Sheldon, Head of Corporate Communications
asheldon@arcutis.com

Investors
Eric McIntyre, Head of Investor Relations
emcintyre@arcutis.com