Journal of the American Medical Association Publishes Roflumilast Cream 0.3% Results from Pivotal DERMIS-1 and -2 Phase 3 Trials in Plaque Psoriasis

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- *Roflumilast cream showed higher efficacy compared to vehicle in both Phase 3 studies on the primary efficacy endpoint of Investigator Global Assessment (IGA) success, with 40% of roflumilast cream treated patients achieving IGA success at eight weeks*
- *Roflumilast cream also demonstrated statistically significant improvements over vehicle in key secondary endpoints with ~70% of patients achieving Intertriginous-IGA success and ~40% of patients achieving PASI-75 at eight weeks*
- *Improvement in itch occurred as early as two weeks and improved consistently through week eight*
- *Once-daily ZORYVE™(roflumilast) is approved for topical use in adults and adolescents with plaque psoriasis, including intertriginous psoriasis, regardless of disease severity*

WESTLAKE VILLAGE, Calif., Sept. 20, 2022 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), an early-stage commercial company focused on developing meaningful innovations in immuno-dermatology, today announced that the *Journal of the American Medical Association* (JAMA) published positive results from two pivotal Phase 3 studies (DERMIS-1 and DERMIS-2) evaluating roflumilast cream 0.3% as a once daily, topical treatment for chronic plaque psoriasis. The study, which was published in the September 20 issue of JAMA, found that treatment with roflumilast cream resulted in significant improvements across multiple efficacy endpoints including plaque clearance and itch at eight weeks in adults and adolescents with plaque psoriasis compared to vehicle. ZORYVE was approved for topical use of plaque psoriasis, including intertriginous psoriasis, for use in adults and adolescents in July 2022.

“These data highlight the robust efficacy of ZORYVE as a novel non-steroidal treatment option for individuals with plaque psoriasis. Both studies met the primary endpoint of IGA success and demonstrated rapid clearance of plaques and reduction of itch,” said Patrick Burnett, M.D., Ph.D., Chief Medical Officer of Arcutis. “Coupled with ZORYVE’s favorable safety and tolerability data, these results reinforce that ZORYVE can offer patients a single topical therapy for use on all psoriasis-affected areas – including hard to treat areas such as elbows and knees and intertriginous areas. We are thrilled that such a prestigious journal has published the results of our pivotal Phase 3 trials.”

“The itch that can occur in patients with chronic plaque psoriasis has negative effects on a patients' quality of life,” said Mark Lebwohl M.D., 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. “The data from these studies demonstrated that ZORYVE was effective in providing a rapid and significant reduction in itch as early as week two, and significantly improved itch-related sleep loss and scores on the Dermatology Life Quality Index (by week six). In addition, ZORYVE rapidly cleared plaques in patients with mild, moderate, and severe disease, as well as in intertriginous areas.”

The “Trials of P **DE**4 inhibition with **R**oflumilast for the **M**anagement of plaque Psorias**IS**” One and Two (or DERMIS-1 and DERMIS-2) were identical Phase 3 randomized, parallel, double-blind, vehicle-controlled, multi-national, multi-center studies in which roflumilast 0.3% cream or matching vehicle cream were applied once daily for eight weeks to subjects age 2 years and above with mild, moderate, or severe chronic plaque psoriasis involving between 2% and 20% body surface area. DERMIS-1 enrolled 439 subjects, and DERMIS-2 enrolled 442 subjects.

In both studies, significantly more patients treated with roflumilast cream reached IGA Success at week eight compared to the control group of vehicle-treated patients (DERMIS-1: 42.4% vs 6.1%; DERMIS-2: 37.5% vs. 6.9%, respectively, P<0.001 for both). Patients with clinically significant itch, as measured by a baseline Worst Itch Numerical Rating Scale (WI-NRS) of greater than or equal to four, achieved a 4-point reduction in WI-NRS at week eight (DERMIS-1: 67.5% vs 26.8%; DERMIS-2: 69.4% vs 35.6%, P<0.001). Improvement in itch was observed by two weeks, the earliest timepoint measured (DERMIS-2: P=0.003), with consistent improvements achieved through week eight.

Other key Phase 3 findings include:

- Roflumilast was highly effective for psoriasis in intertriginous areas (i.e., where two skin areas may touch or rub together), with significantly more roflumilast-treated patients reaching Intertriginous IGA (I-IGA) success at week eight than vehicle-treated patients (DERMIS-1: 71.2% vs. 13.8%; DERMIS-2: 68.1% vs 18.5%, P<0.001 for both), with the vast majority of these patients achieving I-IGA=0 (clear).
- Roflumilast demonstrated improvement in psoriasis over vehicle at all timepoints as measured by the Psoriasis Area Severity Index (PASI). Across both trials, approximately 40% of patients achieved a 75% reduction in PASI scores (PASI-75) by week eight (DERMIS-1: 41.6% vs 7.6%; DERMIS-2: 39.0% vs 5.3%, P<0.001 for both).
- Roflumilast also significantly improved patient-reported signs and symptoms, as measured by significantly greater improvements in the Psoriasis Symptom Diary.
- Roflumilast safety and tolerability were similar to vehicle, including pooled rates of treatment-related treatment-emergent adverse events (AEs) (4.0% roflumilast vs. 3.6% vehicle), any AE leading to discontinuation (1.0% roflumilast vs 1.3%

vehicle) and application site pain (1.0% roflumilast vs 0.3% vehicle). There were no treatment-related serious AEs, and local tolerability was highly favorable for roflumilast as reported by patient and investigator assessment of irritation, burning, and stinging.

To learn more about the data, visit the full article.

About ZORYVE
ZORYVE (roflumilast) cream 0.3% is a next generation topical inhibitor of phosphodiesterase-4 (PDE4) and the first topical PDE4 inhibitor to be approved by the FDA for adults and adolescents with plaque psoriasis, including intertriginous psoriasis.

INDICATION
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 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 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 psoriasis, atopic dermatitis, and seborrheic dermatitis. 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 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 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.

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