New Data Highlighting Itch Reduction with Topical Roflumilast in Multiple Dermatologic Conditions Presented at European Academy of Dermatology and Venereology Congress

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- Topical roflumilast provided significant improvements in severity and burden of itch in Phase 3 plaque psoriasis studies, as well as Phase 2 studies in seborrheic dermatitis and scalp and body psoriasis.
- Quality of life improvements were achieved starting as early as week two
- Pivotal studies support potential use of roflumilast cream as effective and well-tolerated non-steroidal topical therapy for plaque psoriasis

WESTLAKE VILLAGE, Calif., Sept. 30, 2021 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a late-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology to address the urgent needs of patients living with immune-mediated dermatological diseases and conditions, today announced new patient-reported outcome data that show topical roflumilast provides significant reductions in itch, a common and bothersome symptom of multiple dermatologic conditions. Once-daily roflumilast cream reduced both the severity and burden of itch, and improved quality of life, in the DERMIS-1 and DERMIS-2 Phase 3 pivotal studies in chronic plaque psoriasis. In addition, in two separate Phase 2 studies, topical roflumilast foam showed a robust and rapid reduction of itch in scalp and body psoriasis and seborrheic dermatitis. These data were presented at the annual European Academy of Dermatology and Venereology (EADV) Congress (Sept 29 – Oct 2).

"Itch is the most frequently reported symptom associated with dermatologic conditions such as plaque psoriasis, scalp psoriasis and seborrheic dermatitis, severely impacting patients' quality of life. These robust and consistent data across multiple indications demonstrate that topical roflumilast significantly improved both the severity and burden of itch, that symptoms improved quickly and continued improving through the course of treatment," said Patrick Burnett, M.D., Ph.D., FAAD, Chief Medical Officer of Arcutis. "Meaningfully impacting symptoms that matter most to patients, such as itch, is at the core of Arcutis' mission. Topical roflumilast continues to demonstrate strong efficacy with a safety and tolerability profile that, if approved, should enable chronic use and the ability to use across the body."

Dr. Melinda J. Gooderham presented patient-reported outcome data from the DERMIS studies in patients with chronic plaque psoriasis treated with roflumilast cream that showed the mean reduction in Worst-Itch Numeric Rating Scale (WI-NRS) score was significantly greater with roflumilast cream than vehicle at all study timepoints, with improvements achieved as early as two weeks (mean change from baseline of -3.7 and -4.0 for roflumilast cream; -1.4 and -1.7 for vehicle; P<0.0001). In addition, more than two-thirds of patients with a WI-NRS of four or greater at baseline achieved a reduction of four-points or more with roflumilast cream compared to less than one-third of individuals using vehicle at week 8 (67.5% and 69.4% of patients using roflumilast cream compared to 26.8% and 35.6% using vehicle; P<0.0001). Overall quality of life was also improved with the use of once-daily roflumilast cream as measured by the Dermatology Life Quality Index (DLQI) with an improvement of 65.2% from baseline in the DLQI score for roflumilast cream vs 12.7% vehicle in DERMIS-1 and a 69.4% improvement from baseline DLQI score roflumilast cream vs 9.0% vehicle in DERMIS-2 (P<0.0001).

In a separate poster presentation highlighting results from the Phase 2 randomized, double-blind, vehicle-controlled study of roflumilast foam in patients with plaque psoriasis on the scalp and body, 68.2% of patients with a WI-NRS score of four or greater at baseline using roflumilast foam achieved a four point or greater reduction in WI-NRS compared to only 23.1% of patients using vehicle at week eight. These results are consistent with that observed specifically in the scalp with 71.0% of patients with a baseline Scalp Itch (SI)-NRS of four or greater at baseline achieving a four-point or greater improvement in SI-NRS as compared to 18.5% in the vehicle treated group.

Likewise, data presented in a poster presentation from a Phase 2 study of patients with seborrheic dermatitis showed approximately 64.6% of patients with a WI-NRS score of four or greater at baseline using roflumilast foam achieved a four point or greater reduction in WI-NRS compared to only 34.0% of patients using vehicle at week eight.

In these studies, both roflumilast cream and roflumilast foam met their primary endpoints and were generally well-tolerated.

- Roflumilast cream 0.3% met its primary endpoint of Investigator Global Assessment Success rate at week 8 in 42.4% patients compared to a vehicle rate of 6.1% (P<0.0001), and 37.5% compared to a vehicle rate of 6.9% (P<0.0001), in the Phase 3 studies DERMIS-1 and DERMIS-2 respectively (Trials of PDE4 inhibition with Roflumilast for the Management of plaque PsoriasIS" One and Two)
- Roflumilast foam met its primary endpoint in the Phase 2 Scalp and Body study with a Scalp-Investigator Global Assessment success rate of 59.1% patients compared to a vehicle rate of 11.4% (P<0.0001). Of these, 34.3% of patients on roflumilast foam achieved a status of clear.
- Roflumilast foam met its primary endpoint in the Phase 2 seborrheic dermatitis study with 73.8% of roflumilast treated patients achieving IGA success at week 8 vs 40.9% of vehicle-treated patients (P<0.0001). Additionally, 35.5% of patients using roflumilast foam achieved an IGA status of clear at week 8 vs 15.2% of vehicle-treated patients.

About Topical Roflumilast
Arcutis is developing topical cream and foam formulations of roflumilast – a highly potent and selective phosphodiesterase-4 (PDE4) inhibitor being investigated as a once-daily, nonsteroidal, topical treatment for multiple dermatologic conditions. Roflumilast has been approved by the U.S. Food and

Drug Administration (FDA) for oral treatment to reduce the risk of exacerbations of chronic obstructive pulmonary disease (COPD) since 2011. Roflumilast has shown greater potency (25- to 300-fold) than the two other FDA-approved PDE4 inhibitors. PDE4 is an intracellular enzyme that increases the production of pro-inflammatory mediators and decreases production of anti-inflammatory mediators and has been implicated in a wide range of inflammatory diseases including psoriasis, eczema, and COPD. PDE4 is an established target in dermatology, and other PDE4 inhibitors have been approved by the FDA for the topical treatment of atopic dermatitis or the systemic treatment of plaque psoriasis.

About Arcutis

Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a medical dermatology company that champions meaningful innovation to address the urgent needs of patients 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 seven clinical programs for a range of inflammatory dermatological conditions, with our first NDA submission late in the third quarter or early in the fourth quarter of 2021 and three more Phase 3 clinical data readouts anticipated by the end of 2022. The company's lead product candidate, topical roflumilast, has the potential to advance the standard of care for plaque psoriasis, atopic dermatitis, scalp psoriasis, and seborrheic dermatitis. For more information, visit www.arcutis.com or follow Arcutis on LinkedIn and Twitter.

Forward-Looking Statements

This press release contains "forward-looking" statements, including, among others, statements regarding the potential for roflumilast to revolutionize the standard of care in plaque psoriasis and other inflammatory dermatological conditions. These statements involve 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 and you should not place undue reliance on our forward-looking statements. Risks and uncertainties that may cause our actual results to differ include risks inherent in the clinical development process and regulatory approval process, the timing of regulatory filings, and our ability to defend our intellectual property. For a further description of the risks and uncertainties applicable to our business, see the "Risk Factors" section of our Form 10-K filed with U.S. Securities and Exchange Commission (SEC) on February 16, 2021, as well as any subsequent filings with the SEC. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

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