Arcutis Enrolls First Patient in Phase 3 Clinical Trial of Topical Roflumilast Foam (ARQ-154) as a Potential Treatment for Scalp and Body Psoriasis

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- Topical roflumilast potential “Best-in-Class” topical PDE4 inhibitor
- Scalp and body psoriasis affects more than 8 million patients in the U.S.

WESTLAKE VILLAGE, Calif., Aug. 25, 2021 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a late-stage biopharmaceutical company focused on developing meaningful innovations to address the urgent needs of patients living with immune-mediated dermatological diseases and conditions, or immuno-dermatology, today announced it had enrolled the first patient in its single Phase 3 clinical trial evaluating topical roflumilast foam (ARQ-154) as a potential treatment for scalp and body psoriasis. Roflumilast foam is a once-daily topical foam formulation of roflumilast, a highly potent and selective phosphodiesterase type 4 (PDE4) inhibitor, which the Company is developing for both seborrheic dermatitis and scalp and body psoriasis.

“The symptoms of scalp and body psoriasis, including itch and pain, can negatively impact quality of life for the millions of Americans affected. One challenge for patients with scalp psoriasis is that they often require two or more medications for different areas of the body to manage their disease,” said Patrick Burnett, Ph.D., M.D., FAAD, Chief Medical Officer of Arcutis. “In our previous Phase 2b trial, roflumilast foam was demonstrated to be a safe, well-tolerated, and effective potential treatment for scalp and body psoriasis. We are pleased to initiate this Phase 3 trial, as we believe roflumilast foam, if approved, may represent a much-needed, new standard of care for people with scalp and body psoriasis that is suitable for use in hair-bearing areas, unlike creams and ointments, and does not pose the safety concerns typically seen with topical steroids.”

The “**A R**andomized t**R**ial **E**mploying topi**C**al roflumilas**T** foam to treat scalp ps**OR**iasis” (ARRECTOR) study is a parallel group, double blind, vehicle-controlled pivotal Phase 3 study of the safety and efficacy of ARQ-154 0.3% foam or a matching vehicle administered once-daily in approximately 420 subjects with scalp and body psoriasis ages 12 and older. The co-primary endpoints of the study include the proportion of subjects achieving Scalp-Investigator’s Global Assessment (IGA) success and the proportion of subjects achieving Body-IGA success, with IGA success defined as an IGA score of ‘clear’ or ‘almost clear’ plus a 2-point improvement from baseline after eight weeks. Based on prior discussions with the U.S. Food and Drug Administration (FDA), the Company believes that, if successful, this trial will provide sufficient basis to file a supplemental NDA for ARQ-154 in scalp and body psoriasis.

“Our aim at Arcutis is to rapidly innovate topical treatments for dermatological conditions where there has been little to no treatment advances for decades. The initiation of our Phase 3 trial of roflumilast foam for scalp and body psoriasis is an important step forward to addressing an urgent unmet need,” said Frank Watanabe, President and Chief Executive Officer at Arcutis. “The initiation of our ARRECTOR trial is the third of three new Phase 3 programs initiated in 2021 with readouts expected in 2022 and highlights the robustness of our unique dermatology drug development platform.”

About Scalp and Body Psoriasis
Scalp psoriasis is a manifestation of plaque psoriasis characterized by raised, red areas of skin (“plaques”) covered with a silver or white scale that occurs in the hair-bearing area of the scalp and sometimes extending to the forehead, back of the neck, or behind or inside the ears. Patients with scalp psoriasis commonly have plaques on other areas of the body as well. Approximately 40 percent of the estimated 8.6 million Americans with psoriasis have involvement of the scalp, and over a lifetime, up to 80 percent of psoriasis patients may experience scalp involvement. Scalp psoriasis plaques are identical to psoriatic plaques on other areas of the body; however, topical treatment of scalp plaques is complicated by the difficulty of delivering topical drugs under the hair and onto the skin. As with psoriatic plaques on other parts of the body, psoriasis on the scalp is often itchy and is sometimes painful. Scalp psoriasis can also be associated with hair loss, likely due to damage to the hair from excessive scratching, rubbing, or combing of the affected area. Often, patients require two or more medications to manage their disease when they have scalp involvement.

About Topical Roflumilast Foam
Topical roflumilast foam is a once-daily, topical formulation of a highly potent and selective PDE4 inhibitor (roflumilast). The unique foam formulation is designed to penetrate and treat inflammatory dermatoses in hair-bearing areas of the body, such as the scalp, although it is usable on all areas of the body. Roflumilast has been approved by the FDA for oral treatment to reduce the risk of exacerbations of chronic obstructive pulmonary disease (COPD) since 2011. In Phase 3 trials, topical roflumilast cream (ARQ-151) has previously been demonstrated to be a safe, well-tolerated, and effective potential treatment for plaque psoriasis, and Arcutis expects to file an NDA with the FDA for roflumilast cream in late Q3 or early Q4 2021. Roflumilast has shown greater potency (25- to 300-fold) than the two other FDA-approved PDE4 inhibitors for dermatology. 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, atopic dermatitis, 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 and 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 anticipated by the end of 2021 and three more Phase 3 clinical data readouts anticipated over the next 18 months. 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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