Arcutis Completes Enrollment in ARRECTOR Pivotal Phase 3 Trial of Topical Roflumilast Foam in Scalp and Body Psoriasis

April 6, 2022

- Topline data anticipated in late Q3/early Q4
- A total of 432 subjects are enrolled in the ARRECTOR study
- Arcutis progressing topical roflumilast in four dermatological indications
- Over 3 million patients in the U.S. have plaque psoriasis in the scalp

WESTLAKE VILLAGE, Calif., April 06, 2022 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a late-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced the enrollment of the last subject in its ARRECTOR pivotal Phase 3 trial of topical roflumilast foam in adolescents and adults with scalp and body psoriasis. Roflumilast foam is a once-daily, topical formulation of a highly potent and selective phosphodiesterase-4 (PDE4) inhibitor (roflumilast). The foam formulation was designed to treat all areas of the body, including the face and particularly hair-bearing areas such as the scalp. If successful, the Company believes that this trial will provide sufficient basis to file a supplemental New Drug Application (sNDA) in the U.S. for roflumilast foam in scalp and body psoriasis.

Scalp psoriasis occurs in approximately 40% of individuals with plaque psoriasis and can cause physical and emotional distress, with 97% of individuals with scalp psoriasis reporting that the condition impacts their daily life. [i]

"The scalp and hair-bearing areas of the body create unique treatment challenges, not easily solved through creams or ointments, and often requiring patients to use multiple therapies, complicated treatment regimens or resort to expensive systemic or biologic therapies. This can result in lack of compliance to treatment and worsening symptoms. Roflumilast foam has been formulated to overcome these challenges and provide a once-daily treatment option for use on all areas of the body," said Patrick Burnett, MD, PhD, FAAD. "We are proud of the continued execution of our clinical development program as demonstrated by the completion of enrollment in a second pivotal phase 3 program for roflumilast foam this year. More importantly, we move one step closer to providing an important treatment option to millions of individuals impacted by scalp psoriasis."

About ARRECTOR
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 roflumilast foam 0.3% or a matching vehicle administered once-daily in subjects with scalp and body psoriasis ages 12 and older. A total of 432 subjects have enrolled in the study. The co-primary endpoints of the study are 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.

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 plaque psoriasis have involvement of the scalp. 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), which the Company is developing for both seborrheic dermatitis and scalp and body psoriasis. 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. Arcutis has also submitted a New Drug Application (NDA) for a closely related cream formulation of topical roflumilast for the treatment of plaque psoriasis, with a Prescription Drug User Fee Actaction date of July 29, 2022. 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. PDE4 is an intracellular enzyme that increases the production of pro-inflammatory mediators and decreases production of anti-inflammatory mediators; it 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 multiple clinical programs for a range of inflammatory dermatological conditions, with one NDA under review with the FDA and three Phase 3 clinical data readouts anticipated by the end of 2022. The company's lead program, topical roflumilast, has the potential to advance the standard of care for plaque psoriasis of the body and scalp, atopic dermatitis, 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 be approved for the treatment of adults and adolescents with scalp and body psoriasis, the potential to use roflumilast foam over a long period of time, or chronically, the potential to use roflumilast foam anywhere on the body, including the face and scalp, and the potential for roflumilast to advance the standard of care in scalp and body 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 22, 2022, as well as our 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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[i] Crowley J. Scalp psoriasis: an overview of the disease and available therapies. J Drugs Dermatol. 2010 Aug;9(8):912-8. PMID: 20684141.