Arcutis Announces Positive Topline Results from ARRECTOR Pivotal Phase 3 Trial of Roflumilast Foam 0.3% in Scalp and Body Psoriasis

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- Study met both co-primary endpoints and all secondary endpoints
- At week eight, 67.3% of individuals treated with roflumilast foam achieved Scalp-Investigator Global Assessment (S-IGA) Success compared to 28.1% of individuals treated with vehicle
- At week eight, 46.5% of individuals treated with roflumilast foam achieved Body-Investigator Global Assessment (B-IGA) Success compared to 20.8% of individuals treated with vehicle
- Once-daily roflumilast foam demonstrated a favorable safety and tolerability profile

WESTLAKE VILLAGE, Calif., Sept. 26, 2022 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), an early-stage commercial company focused on developing meaningful innovations in immuno-dermatology, today announced positive topline results from the ARRECTOR Pivotal Phase 3 trial evaluating roflumilast foam 0.3%, a once-daily, non-steroidal topical phosphodiesterase-4 (PDE4) inhibitor, for the treatment of adults and adolescents with scalp and body psoriasis. The study met its co-primary endpoints of S-IGA Success and B-IGA Success, and all secondary endpoints.

Specifically, 67.3% of individuals treated with roflumilast foam achieved S-IGA Success compared to 28.1% of individuals treated with a matching vehicle foam at week 8 (P<0.0001), and 46.5% of individuals treated with roflumilast foam achieved B-IGA Success compared to 20.8% of individuals treated with a matching vehicle foam at week 8 (P<0.0001). Roflumilast foam also demonstrated statistically significant improvements compared to vehicle on all secondary endpoints, including scalp itch as measured by Scalp Itch Numeric Rating Scale (SI-NRS) and overall itch as measured by Worst Itch NRS (WI-NRS) at week eight.

Plaque psoriasis impacts 9 million people in the United States and approximately 40 percent of individuals have involvement of the scalp. Scalp psoriasis can have a significant negative impact on quality of life, with individuals feeling shame, embarrassment, or self-consciousness as a result of their scalp disease. Today, scalp psoriasis is most often treated with topical therapies, including corticosteroids and vitamin D analogs, which come with trade-offs between efficacy, tolerability, and long-term usability. Roflumilast foam is a selective and potent PDE4 inhibitor that has been uniquely formulated as an emollient, water-based, moisturizing foam that can be used on the scalp and body.

“Topical therapies are first-line treatments for scalp and body psoriasis, but current options have limitations including aesthetic acceptability, tolerability, effectiveness, and limited duration of use, which can lead to poor outcomes and significantly impact patients’ quality of life. Roflumilast foam provided significant clearance with a rapid onset of action on both the scalp and body as measured by S-IGA and B-IGA respectively,” said Melinda Gooderham, M.Sc., M.D., F.R.C.P.C. Medical Director, SKiN Centre for Dermatology, investigator with Probity Medical Research, and study author. “These data demonstrate that investigational roflumilast foam, if approved, could provide both an effective and well-tolerated new treatment option for scalp and body psoriasis.”

Roflumilast foam was well-tolerated, and the overall safety and tolerability profile was consistent with previously published studies of roflumilast cream 0.3% and foam. The incidence of Treatment Emergent Adverse Events (TEAEs) was low and generally similar between active treatment and vehicle, with most TEAEs assessed as mild to moderate severity. Overall, the most common adverse events in the study population included headache, diarrhea, and COVID-19. In the study, 89.0% of patients who were randomized to roflumilast foam completed the full eight weeks, and few subjects discontinued study drug due to adverse events (2.5% and 1.3% in the roflumilast foam and vehicle groups, respectively).

“We are excited to share these topline results of roflumilast foam, a once-daily non-steroidal treatment option that was designed to overcome limitations of traditional creams and ointments for hair-bearing areas of the body. These pivotal Phase 3 results demonstrate the strong efficacy and tolerability of roflumilast foam for the treatment of scalp and body psoriasis and, with the recently announced Phase 3 results in seborrheic dermatitis, the overall potential for roflumilast foam for the treatment of these skin diseases,” said Patrick Burnett, M.D., Ph.D., F.A.A.D. Chief Medical Officer at Arcutis. “The successive positive results from two pivotal Phase 3 programs for roflumilast foam in two different indications just this year highlights the unique formulation and deep dermatological expertise Arcutis brings to solve unmet needs in medical dermatology.”

The Company already announced plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for roflumilast foam for the treatment of seborrheic dermatitis in Q1 of 2023. The Company believes that the positive results from the ARRECTOR study should provide sufficient bases for a supplemental NDA.

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 were enrolled in the study. The co-primary endpoints of the study were the proportion of subjects achieving S-IGA Success and the proportion of subjects achieving B-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 9 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 drugs through 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
Arcutis is developing topical cream and foam formulations of roflumilast – a highly potent and selective PDE4 inhibitor being investigated as a once-daily, nonsteroidal, topical treatment for multiple dermatologic conditions. PDE4 – an established target in dermatology – is an intracellular enzyme that increases the production of pro-inflammatory mediators and decreases production of anti-inflammatory mediators. Roflumilast cream 0.3% (ZORYVE™) is approved by the FDA for the topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older. Roflumilast foam is a once-daily topical foam formulation of roflumilast which the Company is developing for both seborrheic dermatitis and scalp and body psoriasis.

About ZORYVE
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
This press release contains "forward-looking" statements, including, among others, statements regarding the potential for roflumilast foam to be approved for the treatment of adults and adolescents with scalp and body psoriasis and seborrheic dermatitis, the efficacy and tolerability of roflumilast foam, 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, the potential for roflumilast to advance the standard of care in scalp psoriasis and seborrheic dermatitis. 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 amended, 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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