Arcutis Submits Topical Roflumilast Cream New Drug Application to FDA for the Treatment of Adults and Adolescents with Plaque Psoriasis

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- Plaque psoriasis is a skin disease that affects approximately 8.6 million individuals in the U.S. and presents particular treatment challenges in certain anatomical regions.
- Roflumilast cream, a non-steroidal treatment intended for chronic use, would be the first and only topical PDE4 inhibitor for psoriasis, if approved.
- Roflumilast cream demonstrated statistically significant superiority over vehicle on the primary endpoint of IGA Success and statistically significant improvements in multiple secondary endpoints in pivotal Phase 3 studies.
- Roflumilast cream was generally well-tolerated with a favorable safety and tolerability profile.

WESTLAKE VILLAGE, Calif., Oct. 04, 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 it has submitted a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for roflumilast cream for the treatment of mild-to-severe plaque psoriasis.

Roflumilast cream (ARQ-151) is a once-daily topical formulation of roflumilast, a highly potent and selective inhibitor of phosphodiesterase type 4 (PDE4), an enzyme that drives overactive immune responses. In clinical trials, roflumilast cream demonstrated robust efficacy coupled with favorable safety and tolerability that, if approved, would enable chronic use across the body, without many of the local tolerability issues associated with alternative treatments.

“Today is a critical milestone for Arcutis in our efforts to bring innovative treatments to dermatologists and their patients, and is a reflection of our deep dermatology expertise,” said Frank Watanabe, President and CEO of Arcutis. “Individuals with plaque psoriasis currently do not have topical treatment options that offer a combination of good tolerability and the ability to be used for long periods of time, and that can be used on all parts of the body. If approved, roflumilast cream will be the first and only topical PDE4 inhibitor approved for psoriasis and an important non-steroidal treatment option for the millions of individuals struggling with plaque psoriasis. I want to thank the Arcutis team, as well as the clinical investigators, patients, and partners, for helping us reach this important milestone.”

Psoriasis is a common, non-contagious, immune-mediated skin disease that affects more than 3% of the U.S. population. The majority of patients develop “plaques,” or raised, red areas of skin covered with a silver or white layer of dead skin cells. Psoriatic plaques are often itchy and sometimes painful, and can appear on any area of the body. Plaques in certain anatomical areas present particular treatment challenges, including the face, elbows and knees, scalp, and areas where two skin areas may touch or rub together.

Topical treatments are the mainstay of therapy for the vast majority of psoriasis patients, particularly those with mild-to-moderate disease, as well as many moderate-to-severe patients who use topicals in combination with other treatments. However, existing topical treatments often force physicians and patients to make difficult trade-offs between tolerability and long-term use, requiring the use of multiple products or complicated treatment schedules. Roflumilast cream has been designed to address the challenges posed to dermatologists and patients by existing topical therapies and aims to simplify the overall management of plaque psoriasis.

Arcutis’ submission is supported by positive data from Arcutis’ pivotal Phase 3 program. The DERMIS 1 and DERMIS 2 (Trials of P **DE**4 inhibition with **R**oflumilast for the **M**anagement of plaque Psorias**IS**” One and Two) were identical Phase 3 randomized, parallel, double-blind, vehicle-controlled, multi-national, multi-center studies to evaluate the safety and efficacy of roflumilast cream 0.3%. Roflumilast met its primary endpoint and had an ‘IGA Success’ rate of 42.4% 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 DERMIS 1 and 2 respectively. Roflumilast cream 0.3% also demonstrated statistically significant improvements over vehicle on key secondary endpoints, including on Intertriginous IGA (I-IGA) Success, Psoriasis Area Severity Index-75 (PASI-75), reductions in itch as measured by the Worst Itch-Numerical Rating Scale (WI-NRS), and patient perceptions of symptoms as measured by the Psoriasis Symptoms Diary (PSD). In trials, roflumilast cream was generally well-tolerated with a favorable safety and tolerability profile.

About Roflumilast Cream
Roflumilast Cream is a topical cream formulation of a highly potent and selective PDE4 inhibitor, roflumilast. 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 multiple clinical programs for a range of inflammatory dermatological conditions, with one NDA submission now 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, 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 be approved for the treatment of adults and adolescents with plaque psoriasis, the potential to use roflumilast cream over a long period of time, or chronically, and 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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