FDA Accepts Arcutis Biotherapeutics' New Drug Application for Roflumilast Cream for Adults and Adolescents with Plaque Psoriasis

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- FDA has set a target action date of July 29, 2022
- NDA supported by positive efficacy data from the pivotal Phase 3 DERMIS 1 and DERMIS 2 clinical studies, as well as results from the long-term safety study
- If approved, roflumilast cream would be the first and only topical PDE4 inhibitor for psoriasis

WESTLAKE VILLAGE, Calif., Dec. 22, 2021 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a late-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced the U.S. Food and Drug Administration's (FDA) acceptance for review of the company's new drug application (NDA) for roflumilast cream for the treatment of psoriasis in adults and adolescents. The FDA assigned the application a Prescription Drug User Fee Act (PDUFA) target action date of July 29, 2022.

"With the FDA commencing a review of our NDA filing, we move one step closer to potentially providing a new topical treatment to the millions of Americans living with plaque psoriasis who have limited options beyond steroidal treatments," said Frank Watanabe, President and CEO of Arcutis. "We are proud to be addressing some of the most persistent medical challenges for individuals with serious skin disease and have assembled a strong team that is preparing to commercialize our first product, roflumilast cream, once approved. We look forward to working closely with the FDA during the review process."

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. PDE4 is an established target in dermatology.

"Topical treatments are the standard therapies for the majority of psoriasis patients, but they often come with compromises between efficacy, tolerability and long-term use," said Patrick Burnett, M.D., Ph.D., FAAD, Chief Medical Officer, Arcutis. "With these challenges in mind, we developed roflumilast cream as a formulation for chronic use anywhere on the body, including the face and sensitive intertriginous areas."

Arcutis' NDA submission is supported by positive data from Arcutis' pivotal Phase 3 program and a long-term Phase 2b open label study. 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 Investigator Global Assessment (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 improvement 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 the open-label Phase 2b long-term safety study, durable efficacy of roflumilast cream was observed and the treatment effect was maintained through 52 to 64 weeks. In all trials, roflumilast cream was generally well-tolerated with a favorable safety and tolerability profile. The most common adverse reactions include diarrhea (3%), headache (2%), insomnia (1%), nausea (1%), upper respiratory tract infection (1%), and urinary tract infection (1%).

About Psoriasis
Psoriasis is a common, non-contagious, immune-mediated skin disease that affects more than 8.6 million people in the United States. 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 unique treatment challenges, including the face, elbows and knees, scalp, and intertriginous areas (where two skin areas may touch or rub together.)

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. 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 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, the potential to use roflumilast cream anywhere on the body, including the face and sensitive intertriginous areas, and the potential for roflumilast to advance 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 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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