Arcutis Biotherapeutics Announces Health Canada Accepts for Review the New Drug Submission for Roflumilast Cream for Adults and Adolescents with Plaque Psoriasis

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- *Submission supported by positive clinical data from the pivotal Phase 3 DERMIS-1 and DERMIS-2 clinical studies, as well as results from long-term safety studies*
- *If approved, roflumilast cream would be the first and only topical PDE4 inhibitor for psoriasis in Canada*
- *Target action date of April 30, 2023*
- *Arcutis is in process of establishing Canadian operations*

WESTLAKE VILLAGE, Calif., July 11, 2022 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), today announced that Health Canada has accepted for review the New Drug Submission (NDS) for roflumilast cream 0.3% for the treatment of plaque psoriasis in adults and adolescents. 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. The target action date is April 30, 2023.

“The acceptance for review of our NDS by Health Canada marks an important milestone not only for Arcutis but for the approximately one million Canadians living with plaque psoriasis who currently have limited options when it comes to topical treatments. Canadian dermatologists and their patients have played a critical role in our roflumilast clinical development program with one in four patients in our DERMIS trials enrolled in Canadian sites, so we look forward to providing topical roflumilast to them, if approved,” said Frank Watanabe, president and CEO of Arcutis. “Arcutis is establishing operations in Canada, and we have begun to build out a strong team with deep dermatology and commercialization experience to support the future approval and launch. We look forward to working closely with Health Canada during the review process.”

Arcutis’ NDS submission is supported by positive data from Arcutis’ pivotal Phase 3 program and two long-term open label studies. DERMIS-1 and DERMIS-2 (“Trials of P DE4 inhibition with Roflumilast for the Management of plaque PsoriasIS” 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%. Approximately 1 out of 4 (206/881) patients in DERMIS-1 and DERMIS-2 were enrolled in Canadian sites. 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 DERMIS-2, respectively. Roflumilast cream 0.3% also demonstrated statistically significant improvement over vehicle on 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). Efficacy results for patients continuing treatment with roflumilast cream in open-label extension studies of 6- and 12-month duration were maintained throughout treatment. 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%).

“While topical treatments are the standard therapy for the majority of people with plaque psoriasis, they often come with compromises between efficacy, tolerability, and long-term use,” explained Melinda Gooderham, MSc, MD, FRCPC, Medical Director, SKiN Centre for Dermatology. “If approved in Canada, roflumilast cream has the potential to provide an effective topical treatment option developed as a formulation that can be used for chronic use anywhere on the body, including sensitive areas such as the face, genitals, and intertriginous areas.”

The safety and efficacy of roflumilast cream remain under investigation and market authorization in Canada has not yet been obtained.

A new drug application (NDA) for roflumilast cream for the treatment of plaque psoriasis in adolescents and adults is also under review by the U.S. Food & Drug Administration (FDA). The FDA has set a target action date of July 29, 2022.

Arcutis Canada, Inc., is headquartered in Toronto, Ontario and is led by Jamie Lewis, a highly experienced leader in the Canadian dermatology market, who joined Arcutis in August 2021.

A Media Snippet accompanying this announcement is available by clicking on the image or link below:

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 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 submission now under review with the FDA, one NDS under review with Health Canada, a Phase 3 study completed in seborrheic dermatitis, and two additional Phase 3 clinical data readouts anticipated by 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 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 22, 2022, as amended on March 3, 2022, 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.

Contacts:
Media
Amanda Sheldon, Head of Corporate Communications
asheldon@arcutis.com

Investors
Eric McIntyre, Head of Investor Relations
emcintyre@arcutis.com