



## Arcutis Provides Update on sNDA for Roflumilast Cream 0.15% for Atopic Dermatitis

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WESTLAKE VILLAGE, Calif., July 09, 2024 (GLOBE NEWSWIRE) -- [Arcutis Biotherapeutics, Inc.](#) (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced that the Company has been in communication with the U.S. Food and Drug Administration (FDA) regarding its supplemental New Drug Application (sNDA) for roflumilast cream 0.15% for the treatment of mild to moderate atopic dermatitis (AD) for adults and children down to the age of 6. The FDA has indicated that they are working to finalize the action letter and have not indicated they would extend the Prescription Drug User Fee Act (PDUFA) goal date of July 7, 2024.

"We would like to emphasize that the FDA has not requested any additional information related to our sNDA. This speaks to the completeness and quality of our submission, as we have worked diligently to provide all necessary data and meet all regulatory requirements," said Frank Watanabe, president and CEO of Arcutis. "We are in close contact with the FDA and anticipate receiving our action letter soon. Pending approval, we look forward to delivering this new innovative treatment in roflumilast cream to the millions suffering from atopic dermatitis."

### About Arcutis

Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a commercial-stage 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 has a growing portfolio including two FDA approved products that harness 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 and body psoriasis, atopic dermatitis, and alopecia areata. For more information, visit [www.arcutis.com](http://www.arcutis.com) or follow Arcutis on [LinkedIn](#), [Facebook](#), [Instagram](#) and [X](#).

### Forward-Looking Statements

Arcutis cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements are based on the Company's current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding roflumilast cream 0.15% as a potential treatment for atopic dermatitis, as well as the timing of approval. These statements are subject to 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. Risks and uncertainties that may cause our actual results to differ include risks inherent in our business, reimbursement and access to our products, and the impact of competition and other important factors discussed in the "Risk Factors" section of our Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on February 27, 2024, as well as any subsequent filings with the SEC. You should not place undue reliance on any forward-looking statements in this press release. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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