



Arcutis Announces Data Comparing the Vehicle in Investigational Roflumilast Cream Against a Commercial Ceramide-Containing Moisturizing Cream

December 13, 2021

- Data presented at Revolutionizing Atopic Dermatitis (RAD) Conference
- Vehicle tested was comparable to the moisturizing cream based on primary endpoint of change in transepidermal water loss (TEWL) from baseline at Day 15
- Data provide additional support for ongoing studies of investigational product roflumilast cream in atopic dermatitis

WESTLAKE VILLAGE, Calif., Dec. 13, 2021 (GLOBE NEWSWIRE) -- [Arcutis Biotherapeutics, Inc.](#) (Nasdaq: ARQT), a late-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced data suggesting that Arcutis' proprietary cream vehicle had similar moisturizing properties as a commercially marketed, dermatologist-recommended, ceramide-containing moisturizer in adults with mild eczema. The data from the two groups were similar across patient and healthcare provider assessments of tolerability and aesthetic improvement.

Atopic dermatitis and other forms of eczema have underlying skin barrier defects, which can be further exacerbated by topical medications that harm the skin barrier. Arcutis designed its cream vehicle with both 50% water content and an ultra-mild emulsifier at PH of the skin, as well as excluding propylene glycol, polyethylene glycol, ethanol, or fragrance.

"In this study, both the Arcutis cream vehicle and a dermatologist-recommended, ceramide-containing moisturizing cream were well received by patients, with patients reporting improvements in dryness, redness, irritation and other skin characteristics, as well as positive feedback on the aesthetic properties of the two creams. As a clinician, I was impressed by the moisturizing properties of the Arcutis vehicle," said Zoe Diana Draeos, MD, President and Principal Investigator, Dermatology Consulting Services, PLLC.

Data from the 40-patient, single-site, randomized, double-blinded intraindividual study were presented at the annual RAD Conference. Patients with mild asteatotic eczema applied either roflumilast vehicle cream (without the active ingredient roflumilast) or the ceramide-containing moisturizer to their lower legs (randomized by leg with each subject receiving the ceramide-containing moisturizer and the Arcutis cream vehicle on opposite legs). There was no statistically significant change from baseline in TEWL at Day 15 with either preparation, suggesting that no skin barrier damage was caused by either the vehicle or the moisturizer. TEWL is the most widely-used objective measurement of skin barrier function and can be used as an objective analysis of irritancy potential or protective properties of topical products. Mean TEWL was similar between roflumilast cream vehicle and the ceramide-containing moisturizer throughout the study after day 1.

Patients rated the Arcutis cream vehicle positively and as comparable to the ceramide-containing moisturizer. Specifically, the study found similar improvements in dryness, redness, roughness, tightness, irritation, moisturization, smoothness and overall skin appearance between the two products. In addition, patients consistently rated the aesthetic properties, including spreadability, speed of absorption, feel of skin, and smell, comparably between the Arcutis cream vehicle and ceramide-containing moisturizer. For investigator assessments of erythema, desquamation, roughness and dryness, improvements were observed for both treatments at all timepoints.

"Arcutis is dedicated to bringing meaningful innovation to topicals, where limited innovation has occurred for many years. With six dermatology clinicians on staff, as well as one of the industry's leading topical formulators, founder David Osborne, we have invested in developing therapies that may help address the trade-offs typically seen with many topical dermatology products," said [Patrick Burnett](#), MD, PhD, FAAD, Chief Medical Officer at Arcutis.

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 submitted to 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, and to advance the standard of care for, adults and adolescents with atopic dermatitis, 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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