



Arcutis Announces Positive Topline Results from Pivotal DERMIS-1 and -2 Phase 3 Trials of Topical Roflumilast Cream (ARQ-151) in Plaque Psoriasis

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- Roflumilast cream demonstrated statistically significant superiority over vehicle on primary endpoint of IGA Success
- Favorable safety and tolerability profile in this patient population
- New Drug Application (NDA) submission anticipated in the second half of 2021
- Roflumilast cream potential "Best in Class" topical PDE4 inhibitor, a non-steroidal treatment intended for chronic use
- Plaque psoriasis affects approximately 8.6 million patients in the U.S.
- Company to host a conference call today at 8:30 a.m. EST

WESTLAKE VILLAGE, Calif., Feb. 01, 2021 (GLOBE NEWSWIRE) -- [Arcutis Biotherapeutics, Inc.](https://www.arcutis.com) (Nasdaq: ARQT), a medical dermatology company developing innovative treatments for patients with immune-mediated dermatological diseases and conditions, today announced positive topline results from the DERMIS-1 and DERMIS-2 pivotal Phase 3 studies evaluating roflumilast cream ([ARQ-151](#)) as a potential topical treatment for [plaque psoriasis](#). Roflumilast cream is a once daily topical formulation of roflumilast, a highly potent and selective phosphodiesterase type 4 inhibitor (PDE4).

On the studies' primary endpoint of Investigator Global Assessment (IGA) Success at week 8, roflumilast cream 0.3% had an 'IGA Success' rate in DERMIS-1 of 42.4% compared to a vehicle rate of 6.1% ($P < 0.0001$), and in DERMIS-2 an 'IGA Success' rate of 37.5% compared to a vehicle rate of 6.9% ($P < 0.0001$). IGA Success was defined as an IGA score of clear or almost clear and at least a 2-grade improvement from baseline. 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 DERMIS-1 and DERMIS-2, roflumilast cream was generally safe and well-tolerated. The incidence of Treatment Emergent Adverse Events (TEAEs) was low and similar between active treatment and vehicle, with most TEAEs assessed as mild to moderate in severity. Overall, 90% of patients who were randomized to roflumilast cream in the studies completed the full 8 weeks. Among subjects receiving roflumilast cream, there were only 5 discontinuations in DERMIS-1 due to a TEAE (1.7% of subjects) and 1 discontinuation in DERMIS-2 due to TEAE (0.3% of subjects), and there were no treatment-related Serious Adverse Events (SAEs).

"We are delighted with the strength of these Phase 3 data, which surpassed the already positive results we saw in our Phase 2 studies," said [Patrick Burnett](#), M.D., Ph.D., FAAD, Arcutis' Chief Medical Officer. "These data reinforce our conviction that topical roflumilast is exceptionally well suited to address the unmet needs in the topical treatment of psoriasis, offering an ideal combination of efficacy comparable to the results of published clinical studies of high-potency steroid/calcipotriene or high-potency steroid/tazarotene combination products, the ability to use the drug chronically in any anatomical area, and a very favorable safety and tolerability profile. Based on the strength of these Phase 3 data, we anticipate submission of our NDA to the U.S. FDA in the second half of 2021. Importantly, we want to express our appreciation to the trial participants and the clinical investigators for their commitment to this important research effort."

"The impact of plaque psoriasis extends beyond the serious physical burdens of the disease, with many patients experiencing adverse psychological and social effects as well," said Mark Lebwohl, MD, Professor and Dean for Clinical Therapeutics, Icahn School of Medicine at Mount Sinai, and participant in the trial. "The existing topical treatments prescribed to psoriasis patients have significant shortcomings, which lead to difficult trade-offs between efficacy, safety, and tolerability. These data demonstrate once-daily topical roflumilast cream was well-tolerated and achieved early and significant improvements in psoriasis signs and symptoms, including having a profound impact on itch."

The "Trials of PDE4 inhibition with Roflumilast for the Management of plaque Psoriasis" One and Two (or DERMIS-1 and DERMIS-2) were identical Phase 3 randomized, parallel, double-blind, vehicle-controlled, multi-national, multi-center studies in which roflumilast 0.3% cream or matching vehicle cream were applied once daily for 8 weeks to subjects age 2 years and above with mild, moderate or severe chronic plaque psoriasis involving between 2% and 20% body surface area. DERMIS-1 enrolled 439 subjects, and DERMIS-2 enrolled 442 subjects. The primary endpoint of the studies was IGA Success at week 8. Multiple secondary endpoints were also evaluated, including I-IGA Success, and improvements in Psoriasis Area Severity Index (PASI), itch as measured by the WI-NRS and patient perceptions of symptoms as measured by the Psoriasis Symptoms Diary (PSD). The Company anticipates submission of its NDA to the FDA in the second half of 2021.

Management will host a conference call today at 8:30 a.m. EST to discuss these results. To access the call, please dial (833) 614-1393 (domestic) or (914) 987-7114 (international) prior to the scheduled conference call time and provide the conference ID 8079585. A live webcast of the call will be available on the "Investors" section of the company's website, www.arcutis.com. An archived version of the webcast will be available on the Arcutis website after the call.

About Psoriasis

Psoriasis is a common, non-contagious, immune-mediated skin disease that affects approximately 8.6 million patients in the United States. About 90% of patients develop plaque psoriasis, which is characterized by raised, red areas of skin covered with a silver or white layer of scale. Psoriatic plaques can appear on any area of the body, but most often appear on the scalp, knees, elbows, trunk, and limbs, and are often itchy and sometimes painful. Plaques in certain anatomical areas present particular treatment challenges, including the face, elbows and knees, scalp, and intertriginous regions such as the groin, axillae and inframammary areas.

About Topical 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 - Bioscience, applied to the skin.

Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a late-stage biopharmaceutical company focused on developing and commercializing treatments for unmet needs in immune-mediated dermatological diseases and conditions, or immuno-dermatology. The Company is leveraging recent advances in immunology and inflammation to develop differentiated therapies against biologically validated targets to solve persistent treatment challenges in serious diseases of the skin. Arcutis' robust [pipeline](#) includes four novel drug candidates currently in development for a range of inflammatory dermatological conditions. The Company's lead product candidate, topical roflumilast, has the potential to become the standard of care for plaque psoriasis, atopic dermatitis, scalp psoriasis, and seborrheic dermatitis. For more information, visit www.arcutis.com or follow the company on [LinkedIn](#) and [Twitter](#).

Forward Looking Statements

This press release contains "forward-looking" statements, including, among others, statements regarding roflumilast cream's potential as a treatment for plaque psoriasis; and expectations with regard to the timing of potential NDA submission in 2021. 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-Q filed with U.S. Securities and Exchange Commission (SEC) on November 5, 2020, 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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