



New Topical Roflumilast Data Presented at the European Academy of Dermatology and Venereology (EADV) Congress

September 27, 2021

WESTLAKE VILLAGE, Calif., Sept. 27, 2021 (GLOBE NEWSWIRE) -- [Arcutis Biotherapeutics, Inc.](#) (Nasdaq: ARQT), a late-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology to address the urgent needs of patients living with immune-mediated dermatological diseases and conditions, today announced that four abstracts for Arcutis' topical roflumilast program in psoriasis, scalp and body psoriasis, and seborrheic dermatitis will be presented at European Academy of Dermatology and Venereology (EADV) Congress. Topical roflumilast is a selective and highly potent phosphodiesterase-4 inhibitor being investigated by Arcutis as a non-steroidal topical treatment for multiple inflammatory skin diseases.

"Data continue to demonstrate that topical roflumilast delivers superior efficacy over vehicle across multiple indications while improving the severity and impact of itch," said [Patrick Burnett](#), M.D., Ph.D., FAAD, Chief Medical Officer, Arcutis. "We are proud of the strength of our drug development platform, as demonstrated here with multiple presentations from our DERMIS pivotal trials in psoriasis, as well as Phase 2 data in seborrheic dermatitis, and scalp and body psoriasis."

New data from the DERMIS-1 and DERMIS-2 Phase 3 pivotal trial will be presented in the following oral presentation:

Title: Roflumilast Cream 0.3% Improved the Severity and Impact of Itch in Patients with Chronic Plaque Psoriasis in the Phase 3 DERMIS-1 and DERMIS-2 Studies

Presenting Author: Dr. Melinda J. Gooderham

Time: 2:50 – 3:00 pm CEST/ 8:50 – 9:00 am EDT, September 30, 2021

Location: Room 13

The presentation will include patient-reported outcomes, including itch, which patients with plaque psoriasis report as the most burdensome symptom.

In addition, the following posters will be electronically available for the entirety of the conference:

Title: Once-Daily Roflumilast Cream 0.3%, a Potent Phosphodiesterase-4 Inhibitor, Provided Safe and Effective Treatment of Psoriasis in the DERMIS-1 and DERMIS-2 Phase 3 Trials

Presenting Author: Dr. Mark Lebwohl

Title: Once-daily Roflumilast Foam 0.3% Improves Severity and Burden of Itch in Patients with Scalp and Body Psoriasis in a Randomized, Double-blind, Vehicle-controlled Phase 2b Study

Presenting Author: Dr. Angela Y. Moore

Title: Randomized, Double-blind, Vehicle-controlled Phase 2a Study Evaluating Once Daily Roflumilast Foam 0.3% in Patients with Moderate to Severe Seborrheic Dermatitis

Presenting Author: Dr. Matthew Zirwas

About Topical Roflumilast

Arcutis is developing topical cream and foam formulations of roflumilast – a highly potent and selective phosphodiesterase-4 (PDE4) inhibitor being investigated as a once-daily, nonsteroidal, topical treatment for multiple dermatologic conditions. 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

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 seven clinical programs for a range of inflammatory dermatological conditions, with our first NDA submission late in the third quarter or early in the fourth quarter of 2021 and three more Phase 3 clinical data readouts anticipated by the end of 2022. The company's lead product candidate, 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 16, 2021, 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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