New Data from Arcutis' Topical Roflumilast Clinical Program Presented at the European Academy of Dermatology and Venereology (EADV) Congress

September 6, 2022

WESTLAKE VILLAGE, Calif., Sept. 06, 2022 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), an early-stage commercial company focused on developing meaningful innovations in immuno-dermatology, today announced that four abstracts for Arcutis' topical roflumilast program in seborrheic dermatitis and psoriasis will be presented at European Academy of Dermatology and Venereology (EADV) Congress, held September 7-10, 2022, in Milan and virtually. Specifically, new data from the STRATUM Phase 3 pivotal trial of roflumilast foam in seborrheic dermatitis will be presented in a late-breaking news session.

"We are excited that the full results of our STRATUM Phase 3 trial of roflumilast foam in seborrheic dermatitis will be presented orally in a late breaking session, and two additional abstracts on our phase 2 program were accepted as posters. This highlights the large unmet need for novel non-steroidal treatment options for millions of individuals suffering from this condition and the interest from the dermatological community in our investigational therapy," said Patrick Burnett, M.D., Ph.D., FAAD, Chief Medical Officer, Arcutis. "We also look forward to sharing the robust safety, efficacy, and tolerability of ZORYVE roflumilast cream in treating sensitive areas, including the face, intertriginous, and genital areas from our phase 3 program in plaque psoriasis."

The oral presentation of the STRATUM Phase 3 pivotal trial of roflumilast foam in seborrheic dermatitis will be presented:

> **D2T01.3: Late breaking news: Efficacy and safety of roflumilast foam 0.3% in patients with seborrheic dermatitis in a phase 3 trial**
> Presenting Author: Dr. Andrew Blauvelt
> Time: Friday, Sept 9, 2022, 14.15 - 17.30 pm CEST; 8:15-10:30 am ET
> Room: Golden Plenary

In addition, the following posters will be electronically available for the entirety of the conference and online through November 30, 2022.

> Title: **Efficacy and safety by race and ethnicity in a randomized, double-blind, vehicle-controlled phase 2a study evaluating once-daily roflumilast foam 0.3% in patients with seborrheic dermatitis**
> ePoster P0234
> Kircik, L et al.

> Title: **Long-term safety and efficacy of roflumilast foam 0.3% in patients with seborrheic dermatitis in a 24-52-week, open-label phase 2 trial**
> ePoster P0236
> Alexis, A et al.

> Title: **Efficacy and tolerability of roflumilast cream 0.3% in patients with chronic plaque psoriasis involvement on the face, intertriginous, or genital areas: Pooled Results from Phase 3 trials (DERMIS-1 and DERMIS-2)**
> ePoster P1499
> Ferris, L et al.

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. PDE4 – an established target in dermatology – is an intracellular enzyme that increases the production of pro-inflammatory mediators and decreases production of anti-inflammatory mediators. Roflumilast cream 0.3% (ZORYVE™) is approved by the FDA for the topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older. Roflumilast foam is a once-daily topical foam formulation of roflumilast which the Company is developing for both seborrheic dermatitis and scalp and body psoriasis.

About ZORYVE
ZORYVE (roflumilast) cream 0.3% is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older.

IMPORTANT SAFETY INFORMATION
The use of ZORYVE is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C).

The most common adverse reactions (≥1%) include diarrhea (3%), headache (2%), insomnia (1%), nausea (1%), application site pain (1%), upper respiratory tract infection (1%), and urinary tract infection (1%).

Please see full Prescribing Information.

About Arcutis
Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a 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 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 including scalp psoriasis, atopic dermatitis, and seborrheic dermatitis. For

more information, visit www.arcutis.com or follow Arcutis on LinkedIn, Facebook, and Twitter.

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 the use of ZORYVE in patients with plaque psoriasis in intertriginous areas; the potential of real-world use results of roflumilast cream, the potential for roflumilast foam to be approved for the treatment of adults and adolescents with seborrheic dermatitis, the potential to use roflumilast foam over a long period of time, or chronically, the potential to use roflumilast foam anywhere on the body, including the face and scalp, anticipated submission of the NDA and the potential for roflumilast to advance the standard of care in seborrheic dermatitis and other inflammatory dermatological conditions. 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, the impact of competition and other important factors discussed in the "Risk Factors" section of our Form 10-K filed with U.S. Securities and Exchange Commission (SEC) on February 22, 2022, as amended, 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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