Arcutis to Present New Topical Roflumilast Data Including Late Breaking Atopic Dermatitis Pivotal Trial Data During the American Academy of Dermatology (AAD) Annual Meeting

March 9, 2023

- Late breaking session to highlight new data from the INTEGUMENT Phase 3 trials evaluating roflumilast cream in atopic dermatitis
- New national survey insights depicting disease burden, path to diagnosis and treatment patterns for seborrheic dermatitis
- New clinical safety and efficacy data of topical roflumilast in patients with seborrheic dermatitis and psoriasis
- New safety and pigmentation data for roflumilast foam in individuals with diverse skin types presented at 19th Annual SOCS Symposium

WESTLAKE VILLAGE, Calif., March 09, 2023 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), an early commercial-stage company focused on developing meaningful innovations in immuno-dermatology, today announced six presentations at the 2023 American Academy of Dermatology (AAD) annual meeting, which will take place in New Orleans from March 17-21, 2023 and an additional poster at the SOCS Symposium on March 16, 2023. Among these will be the presentation of late-breaking clinical data on roflumilast cream 0.15% in patients aged 6 years and older with atopic dermatitis from the pivotal Phase 3 INTEGUMENT-1 and INTEGUMENT-2 Phase 3 trials.

“The breadth of our scientific data being presented at AAD underscores Arcutis’ commitment to bring meaningful innovation to immuno-dermatology. We are excited by the acceptance of our late-breaking data from the INTEGUMENT pivotal Phase 3 trials, which build strong evidence for the potential of roflumilast cream as an effective once-daily, steroid-free treatment for atopic dermatitis,” said Patrick Burnett, MD, PhD, FAAD, Chief Medical Officer, Arcutis. “Medical meetings like AAD provide an important opportunity for scientific exchange, and we look forward to sharing these findings, and findings from our other topical roflumilast studies, as well as new survey data in seborrheic dermatitis, with the dermatology community.”

Presentation details follow:

- Late Breaking Data Presentation

  Late breaking news: Efficacy and Safety of Roflumilast Cream 0.15% in Adults and Children aged ≥ 6 With Mild to Moderate Atopic Dermatitis in Two Phase 3 Trials (INTEGUMENT-1 and INTEGUMENT-2)

  Presenting Author: Dr. Lawrence F. Eichenfield
  Time: March 18, 2023, 11:00-11:10 am CT
  Room: Theater B

- Poster Presentations

  Patient and Healthcare Provider Perspective on the Disease Burden of Seborrheic Dermatitis in the United States: Results From a National Survey
  Presenting Author: Dr. Raj Chovatiya
  Time: Friday, March 17, 2023, 3:20-3:25 pm CT
  Room: Poster Center 2
  ePoster 42842

  Patient and Healthcare Provider Perspectives on the Path to Diagnosis of Seborrheic Dermatitis: Results From a National Survey of Adults With Seborrheic Dermatitis in the United States
  Presenting Author: Dr. Raj Chovatiya
  Time: Friday, March 17, 2023, 3:25-3:30 pm CT
  Room: Poster Center 2
  ePoster 42848

  Patient and Healthcare Provider Perspective on the Treatment Patterns and Patient Satisfaction of Seborrheic Dermatitis in the United States: Results From a National Survey
  Presenting Author: Dr. Raj Chovatiya
  Time: Friday, March 17, 2023, 3:30-3:35 pm CT
  Room: Poster Center 2
  ePoster 42861

In addition, the following posters will be electronically available for the entirety of the conference and online beginning Friday, March 17, 2023.

Efficacy and Safety of Roflumilast Cream 0.3% in Patients With Chronic Plaque Psoriasis: Pooled PASI and PASI-HD Results From the DERMIS-1 and DERMIS-2 Phase 3 Trials
Papp, K et al.
ePoster 42828

Efficacy and Safety of Roflumilast Foam 0.3% in Patients With Seborrheic Dermatitis in a Phase 3 Trial: Assessment of Pruritus
Blauvelt, A et al.
ePoster 42835

The following poster will be available during the 19th Annual SOCS Symposium on Wednesday, March 16, 2023.

Safety and Pigmentation Changes From a Phase 3 Trial of Roflumilast Foam 0.3% in Patients With Seborrheic Dermatitis
Alexis, A 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 cream is being evaluated at lower doses for atopic dermatitis: 0.15% for adults and children 6 years of age and older, and 0.05% for children aged 2 to 5 years. Roflumilast foam 0.3% 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 has a growing portfolio that 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 and body psoriasis, atopic dermatitis, seborrheic dermatitis, and alopecia areata. 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 potential for ZORYVE to simplify disease management for care of plaque psoriasis; the potential to use roflumilast foam for pruritus, the potential for roflumilast to advance the standard of care in atopic dermatitis, 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 28, 2023, 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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