Arcutis Announces Acceptance of Late Breaking Abstract in Atopic Dermatitis Among Five New Topical Roflumilast Data Being Presented at the American Academy of Dermatology Annual Meeting

March 4, 2024

- Late breaking sessions to highlight new data from the INTEGUMENT-PED trial evaluating roflumilast cream 0.05% in children ages 2-5 with atopic dermatitis
- New patient-reported outcomes including pruritus data from two pooled Phase 3 trials (DERMIS-1 and DERMIS-2) of ZORYVE® (roflumilast) cream 0.3% in plaque psoriasis
- New efficacy and patient-reported outcome data of ZORYVE (roflumilast) topical foam, 0.3%, in seborrheic dermatitis and investigational roflumilast foam in scalp and body psoriasis

WESTLAKE VILLAGE, Calif., March 04, 2024 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced five presentations at the 2024 American Academy of Dermatology (AAD) annual meeting, which will take place in San Diego, CA from March 8 - 12, 2024. Among these presentations will be late-breaking clinical data on roflumilast cream 0.05% in patients 2 to 5 years of age with mild to moderate atopic dermatitis from the pivotal INTEGUMENT-PED Phase 3 randomized controlled trial.

“Our significant presence at this year’s AAD is a testament to our commitment to bringing meaningful innovation in immuno-dermatology, and building on the body of evidence supporting our topical roflumilast development program. In particular, we are excited to be participating in the late breaking data presentations with new results from INTEGUMENT-PED, as part of our atopic dermatitis clinical program,” said Patrick Burnett, MD, PhD, FAAD, chief medical officer, Arcutis. “We appreciate the opportunity to participate in the AAD and other medical meetings to engage with our peers and progress the medical dermatology field.”

Presentation details follow:

- Late Breaking Data Presentation
  Efficacy and Safety of Once-Daily Roflumilast Cream 0.05% in Pediatric Patients 2 to 5 Years of Age With Mild to Moderate Atopic Dermatitis (INTEGUMENT-PED): A Phase 3 Randomized Controlled Trial
  Presenting Author: Dr. Lawrence Eichenfield
  Time: March 10, 2024, 2:30 PM PT
  Room: 20BCD

- Oral Poster Presentation
  Roflumilast Cream 0.3% in Patients With Psoriasis: Improvement in Patient Reported Outcomes and Pruritus From Two Pooled Phase 3 Trials (DERMIS-1/DERMIS-2)
  Presenting Author: Dr. Mark Lebwohl
  Time: March 9, 2024, 3:25 PM PT
  Room: Upper Level, Sails Pavilion, Poster Center 2

The following posters will be electronically available for the entirety of the conference and online beginning Friday, March 8, 2024:

Pooled Efficacy, Patient-Reported Outcomes, and Safety of Roflumilast Cream 0.15% From the INTEGUMENT-1 and INTEGUMENT-2 Phase 3 Clinical Trials of Adults and Children With Atopic Dermatitis
Simpson, E et al.
ePoster 53863

Roflumilast Foam 0.3% Once Daily in Patients With Seborrheic Dermatitis: Improvement in Patient Reported Outcomes and Pruritus From a Phase 3 Trial (STRATUM)
Bhatia, N et al.
ePoster 53894

Patient-Reported Outcomes With Roflumilast Foam 0.3% in Patients With Scalp and Body Psoriasis in the Phase 3 ARRECTOR Trial
Gooderham, M et al.
ePoster 53817

Roflumilast Cream 0.3% in Patients With Psoriasis: Improvement in Patient Reported Outcomes and Pruritus From Two Pooled Phase 3 Trials (DERMIS-1/DERMIS-2)
Lebwohl, M et al.
ePoster 53025

About Arcutis
Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a commercial-stage 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 including two FDA approved products that harness 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, and alopecia areata. For more information, visit www.arcutis.com or follow Arcutis on LinkedIn, Facebook, and X.

INDICATIONS
ZORYVE cream is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older.

ZORYVE foam, 0.3%, is indicated for treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older.

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

Flammability: The propellants in ZORYVE foam are flammable. Avoid fire, flame, and smoking during and immediately following application.

The most common adverse reactions (≥1%) for ZORYVE cream include diarrhea (3.1%), headache (2.4%), insomnia (1.4%), nausea (1.2%), application site pain (1.0%), upper respiratory tract infection (1.0%), and urinary tract infection (1.0%).

The most common adverse reactions (≥1%) for ZORYVE foam include nasopharyngitis (1.5%), nausea (1.3%), and headache (1.1%).

Please see full Prescribing Information for ZORYVE foam and full Prescribing Information for ZORYVE cream.

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 topical roflumilast to advance the standard of care in 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 27, 2024, 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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