Arcutis Highlights Growth Opportunities at Investor Day in Advance of 2022 Catalysts

March 28, 2022

- Differentiated profile of topical roflumilast aligned with unmet needs in multiple inflammatory dermatoses
- Well-prepared for the Company's potential first launch ahead of PDUFA target action date of July 29
- Clinical program for topical roflumilast continues to advance with announcement of new long-term Phase 2 data in seborrheic dermatitis and three Phase 3 data readouts expected in 2022
- Topical roflumilast has potential to generate sales of ~$2 billion to ~$4 billion in the U.S. dermatology segment alone by 2030
  Early-stage pipeline progressing with ARQ-255 expected to enter the clinic in 2022 in alopecia areata
- Live webcast and archived replay of Investor Day available in **IR section** of Arcutis website

WESTLAKE VILLAGE, Calif., March 28, 2022 (GLOBE NEWSWIRE) -- **Arcutis Biotherapeutics, Inc.** (Nasdaq: ARQT), a late-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, outlines the company's growth strategy and continued clinical progress of its broad immuno-dermatology pipeline during today's Investor Day in Boston, MA at 10:30 a.m. EST.

The meeting features presentations followed by a Q&A session led by Arcutis executives, Frank Watanabe, President and Chief Executive Officer; Patrick Burnett, MD, PhD, FAAD, Chief Medical Officer; Ken Lock, Chief Commercial Officer; and Scott Burrows, Chief Financial Officer.

"This year will be transformational for Arcutis. We have the right strategy in place to build on our sustained track record of clinical execution, commercialize our first product, and partner with dermatologists to tackle some of the most persistent challenges in immune-mediated dermatological diseases and conditions," said Frank Watanabe. "We look forward to continuing to advance the development of topical roflumilast across multiple potential indications, as well as building out our early therapeutic pipeline, with our investigational therapy for alopecia areata expected to enter the clinic later this year."

The Investor Day will highlight multiple programs, illustrating the significant opportunity in Arcutis' portfolio and its value-creating potential:

Long-Term Value Creation for Shareholders

- Topline Phase 3 readouts of topical roflumilast expected in atopic dermatitis, seborrheic dermatitis, and scalp psoriasis in 2022, with continued pipeline progress beyond topical roflumilast
- Roflumilast cream and foam could emerge as treatment options for the approximately 7 million topically treated patients in dermatologist offices in the U.S. today
- Strong and expanding patent portfolio for topical roflumilast with protection expected until at least 2037
- Topical roflumilast has potential to generate sales of $1.8 billion to $3.8 billion in U.S. alone in the dermatology segment, with significant incremental opportunity to reach patients treated by physicians outside the dermatology setting
- Cash runway into 2024 including recently closed non-dilutive financing from SLR Capital Partners, sufficient to fund launch and ongoing Phase 3 programs
- Continued commitment to Environmental, Social, and Governance (ESG) programs

Roflumilast Cream in Plaque Psoriasis

- Robust efficacy in both Phase 3 studies, with favorable safety and tolerability profile in once-a-day cream
- New pooled data results from Phase 3 trials presented at American Academy of Dermatology (AAD) demonstrate consistent efficacy regardless of disease severity
- Being studied on all areas of the body, including the face and sensitive intertriginous areas (where two skin areas may touch or rub together)
- With the potential to simplify treatment in plaque psoriasis, the clinical profile of roflumilast cream is highly aligned with interests of healthcare professionals, patients, and payors
- Large pool of currently treated and readily addressable patients

Roflumilast Cream in Atopic Dermatitis

- Significant opportunity in underserved, growing atopic dermatitis market
- Consistent evidence of efficacy results across endpoints in Phase 2 trial
- Arcutis cream vehicle is uniquely formulated as a moisturizing and non-irritating cream, providing additional benefit to atopic dermatitis patients
- Topline Phase 3 data from large, well-powered INTEGUMENT-1 and -2 studies expected in subjects aged six and older by end of 2022

Roflumilast Foam in Seborrheic Dermatitis & Scalp Psoriasis

- Topline Phase 3 data expected by mid-year in seborrheic dermatitis and by late third quarter or early fourth quarter of 2022 in scalp psoriasis
- Significant unmet need in seborrheic dermatitis with similar U.S. prevalence in dermatologists' offices as psoriasis
- New Phase 2 long-term data from a total of 400 subjects in seborrheic dermatitis demonstrated efficacy up to 52 weeks that was consistent with Week 8 efficacy from Phase 2, as well as favorable safety and tolerability profile
    - Over three quarters (76%) of subjects achieved Investigator Global Assessment (IGA) of completely clear or almost clear at Week 24
    - In a cohort treated for 52 weeks, 82% of subjects achieved IGA of completely clear or almost clear at Week 52
    - Treatment-emergent adverse events and discontinuations due to adverse events were low. Safety and tolerability with long-term exposure to roflumilast foam consistent with already completed short-term studies and supports long-term use
- Patient insights study reinforces need to simplify treatment regimen and interest from physicians and patients in new treatment options

Early Pipeline

- Advancing multiple preclinical programs in dermatology, including projects in acne, palmoplantar psoriasis, nail psoriasis, and rosacea
- Continuing to look for strategic in-licensing or business development opportunities to bring in potential best-in-class, validated targets
- ARQ-255, a topical janus kinase 1 (JAK1) inhibitor therapy formulated to reach deeper into the skin, is expected to enter the clinic in alopecia areata in 2022

A link to register for the event is available here. The event will also be simultaneously webcast at the "Events" section of the Company's website, with the presentation made available at the start of the live webcast. An archived replay of the webcast will be available on the Arcutis website following the event.

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 multiple clinical programs for a range of inflammatory dermatological conditions, with one NDA under review with the FDA and three Phase 3 clinical data readouts anticipated by the end of 2022. The company's lead program, topical roflumilast, has the potential to advance the standard of care for plaque psoriasis of the body and scalp, atopic dermatitis, 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. Forward-looking statements include all statements other than statements of historical fact contained in this presentation, including information concerning our current and future financial performance, business plans and objectives, current and future clinical and preclinical development activities, current and future commercialization activities and their potential success, timing and success of our ongoing and planned clinical trials and related data, the timing of announcements, updates and results of our clinical trials and related data, our ability to obtain and maintain regulatory approval, the potential therapeutic benefits and economic value of our product candidates, competitive position, industry environment, and potential market opportunities. 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 our 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.

Contacts:

Media
Amanda Sheldon, Head of Corporate Communications
asheldon@arcutis.com

Investors
Eric McIntyre, Head of Investor Relations
emcintyre@arcutis.com