Arcutis Begins Enrolling Phase 1a/1b Study Evaluating ARQ-234, a CD200R Agonist, in Healthy Volunteers and Adults With Atopic Dermatitis

March 3, 2026

- Phase 1a/1b, first-in-human study to evaluate safety and tolerability for investigational ARQ-234 in healthy volunteers and adults with moderate to severe atopic dermatitis
- ARQ-234 is a potent fusion-protein agonist of the CD200 receptor (CD200R), an immune-regulatory checkpoint involved in maintaining immune balance

WESTLAKE VILLAGE, Calif., March 03, 2026 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced that the first participant has been enrolled in a Phase 1a/1b, double-blind, randomized, placebo-controlled study, ARQ-234-131, evaluating the safety and tolerability of ARQ-234. The investigational biologic, administered as a subcutaneous injection, is being evaluated in sequential cohorts, with single-ascending-dose cohorts in healthy volunteers and adults with moderate to severe atopic dermatitis, followed by multiple-ascending-dose cohorts and a small proof-of-concept cohort in the adults with atopic dermatitis.

ARQ-234 is a fusion protein designed to selectively activate the CD200 receptor (CD200R), an immune-regulatory checkpoint that helps regulate immune responses. By binding to CD200R, ARQ-234 is intended to reduce overactive immune responses and help restore balance.

“There is a significant opportunity to advance new treatments for moderate to severe atopic dermatitis that address the underlying immune dysregulation and provide long-term symptom control. We believe ARQ-234 and its CD200R immune-checkpoint agonist mechanism is a very promising pathway to address critical unmet needs,” said Patrick Burnett, MD, PhD, FAAD, chief medical officer at Arcutis. “Our team’s deep dermatology expertise and extensive biologics experience uniquely position us to progress this asset efficiently through early clinical development. Advancing ARQ-234 into the clinic reflects our continued commitment to expanding innovation for people living with this chronic condition.”

About ARQ-234-131
This Phase 1a/1b, double-blind, randomized, placebo-controlled, sequential assignment study will enroll approximately 125 participants aged 18 to 65 years, including healthy volunteers and individuals with moderate to severe atopic dermatitis. The first-in-human study consists of three parts with staggered initiation: Part A (Phase 1a, single-ascending dose) includes healthy participants and adults with moderate to severe atopic dermatitis assessed at 16 weeks; Part B (Phase 1b, multiple-ascending dose) includes participants with atopic dermatitis assessed at 30 weeks; and Part C (Phase 1b, proof-of-concept expansion) includes participants with atopic dermatitis assessed at 30 weeks. ARQ-234 will be administered as a subcutaneous injectable solution.

The study’s primary objectives are to evaluate the safety and tolerability of ARQ-234 and clinical improvement in adults with moderate to severe atopic dermatitis. The study’s secondary objective is to evaluate pharmacokinetics across single and multiple-dose levels.

About Atopic Dermatitis
Atopic dermatitis is the most common type of eczema, affecting approximately 16.5 million adults in the United States. Atopic dermatitis is a chronic, relapsing, and genetically predisposed inflammatory skin disease that has unique clinical presentations across the lifespan. The disease typically appears as a red, intensely itchy rash that can occur anywhere on the body and is associated with significant itch, sleep disturbance, and impacts on quality of life across all ages.

About ARQ-234
ARQ-234 is a fusion protein agonist of the CD200 receptor (CD200R), an immunoregulatory checkpoint involved in maintaining immune balance. Checkpoint agonism is an emerging immunomodulatory approach to amplify pathways that inhibit overactive immune cells and suppress unwanted immune responses. ARQ-234 binds to CD200R and has the potential to restore immune homeostasis by inducing inhibitory signaling on immune cells.

CD200R has been validated as a target in atopic dermatitis, with preclinical data for ARQ-234 and clinical data for a similar molecule that previously advanced to clinical development by another company. Ducentis (acquired by Arcutis in 2022) completed preclinical comparisons of ARQ-234 against the clinically validated CD200R antibody. The data compare favorably across key metrics including potency, efficacy, and pharmacokinetics. The data also indicate potential differentiation from the clinically validated CD200R antibody with a longer half-life and a higher steady-state volume of distribution.

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 of advanced targeted topicals approved to treat three major inflammatory skin diseases. Arcutis’ unique dermatology development platform coupled with our dermatology expertise allows us to develop differentiated therapies against biologically validated targets, and has produced a robust pipeline for a range of inflammatory dermatological conditions. For more information, visit www.arcutis.com or follow Arcutis on LinkedIn, Facebook, Instagram and X.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. For example, 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 ARQ-234 to achieve the desired clinical trial results and to advance the standard of care in atopic dermatitis. 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 the U.S. Securities and Exchange Commission (SEC) on February 25, 2026, as well as any subsequent filings with the SEC. Any forward-looking statements that the company makes in this press release are made pursuant to the Private Securities Litigation Reform Act of 1995, as amended, and speak only as of the date of this press release. Except as required by law, 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
media@arcutis.com

Investors
Brian Schoelkopf, Head of Investor Relations
ir@arcutis.com