Arcutis Completes Enrollment of Phase 1b Alopecia Areata Study Evaluating ARQ-255

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- ARQ-255 is a topical Janus kinase 1 (JAK1) inhibitor suspension formulated as a potential topical treatment for alopecia areata
- Proprietary Deep Dermal Drug Delivery (4D) technology formulated to deliver drug deep into the skin to the base of the hair follicle where alopecia areata inflammation occurs
- Phase 1b results expected first half of 2025

WESTLAKE VILLAGE, Calif., Sept. 05, 2024 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced the enrollment of the last subject in the Phase 1b study evaluating ARQ-255, a topical suspension of ivarmacitinib, a potent and selective JAK1 inhibitor, for the treatment of alopecia areata. ARQ-255 has been specifically formulated with Arcutis' proprietary 4D technology to deliver drug deep into the skin to the base of the hair follicle, the site of the inflammation that underlies alopecia areata.

"Alopecia areata affects approximately 1 in 500 people, yet today there are no FDA approved topical treatments for this devastating condition," said Patrick Burnett, MD, PhD, FAAD, chief medical officer at Arcutis. "The safety, tolerability, and pharmacokinetics data generated from this first-in-human study will provide valuable information to inform our ARQ-255 clinical development program and advance our vision of bringing innovation to the treatment of immune-mediated skin conditions where there has been little advancement in decades."

The Phase 1b, vehicle-controlled, double-blind, multicenter study is evaluating the safety, tolerability, pharmacodynamics, and pharmacokinetics of ARQ-255 topical suspension or vehicle in healthy adult volunteers and individuals with patchy alopecia areata (n=44). Results from the study are expected to be reported in the first half of 2025.

About ARQ-255
ARQ-255, or topical ivarmacitinib suspension, is a topical JAK1 inhibitor therapy for alopecia areata. Topical treatment of alopecia areata is challenging due to the depth of inflammation. ARQ-255 has been uniquely formulated to deliver drug deeper into the skin to reach the site of inflammation at the base of the hair follicle in alopecia areata.

About Alopecia Areata
Alopecia areata is an autoimmune condition that affects about 1 in 500 adults and occurs in individuals of all ages, sexes, and ethnic groups. In alopecia areata, the immune system attacks the body's own hair follicles—leading to the development of patches of hair loss (alopecia) on the scalp, face, and other areas of the body. Typically, these bald patches appear suddenly and, in some patients, can progress to involve the entire body. Recurrence is common and many patients will experience several episodes during their lifetime.

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 three 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, Instagram and X.

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 timing and potential for clinical results for ARQ-255 and for the continuation of the clinical development program. 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, and 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 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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