Arcutis Initiates Patient Enrollment in the Phase 2b Portion of the Phase 1/2b Study Evaluating ARQ-252 in Chronic Hand Eczema

July 13, 2020

- ARQ-252 is a potent and highly selective topical JAK1 inhibitor offering potential safety advantages over less selective JAK inhibitors
- Company expects topline data in the second half of 2021

WESTLAKE VILLAGE, Calif., July 13, 2020 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a medical dermatology company developing innovative treatments for patients with immune-mediated dermatological diseases and conditions, today announced that it initiated enrollment in the Phase 2b portion of the Phase 1/2b study of ARQ-252, a potent and highly selective topical small molecule inhibitor of Janus kinase type 1 (JAK1), in adult patients with chronic hand eczema. Topline data from this trial are expected in the second half of 2021.

“More than eight million people in the U.S. suffer from hand eczema, a chronic skin disease that can cause significant skin irritation and discomfort and negatively impact a person’s quality of life,” said Howard Welgus, M.D., Arcutis’ Chief Medical Officer. “Current treatments often fall short, resulting in patients and physicians making trade-offs between efficacy and tolerability. We are pleased to begin enrollment in this important study of ARQ-252 in adult patients with chronic hand eczema. We believe that, due to its demonstrated potency and high selectivity for JAK1 over JAK2, ARQ-252 has the potential to provide the level of efficacy patients desperately want without causing the side effects that may be associated with other less selective JAK inhibitors, thereby eliminating the need to compromise between safety, efficacy, and tolerability.”

In April, Arcutis began enrolling patients in the Phase 1 portion of the Phase 1/2b study to assess the safety, tolerability, and pharmacokinetics of once daily application of ARQ-252 cream 0.3% to both hands for two weeks in six subjects with chronic hand eczema. The Phase 2b portion of this study will assess the safety and efficacy of ARQ-252 cream 0.1% once daily and ARQ-252 cream 0.3% once daily or twice daily versus vehicle applied once daily or twice daily for 12 weeks to patients with chronic hand eczema. The Company expects topline data in the second half of 2021.

About Hand Eczema
Hand eczema is a common inflammatory skin disease with prevalence estimated at up to 2.5% of the population. Symptoms of hand eczema can vary by severity and include redness, fluid filled blisters or bumps, scaling, cracking, itching and pain occurring on the hands. It may occur in various forms, incorporating dyshidrotic eczema, an immune disease possibly related to atopic dermatitis; irritant contact dermatitis of the hands, which may be caused by occupational irritants; allergic contact dermatitis of the hands, which is caused by an allergic reaction; atopic hand dermatitis, which is atopic dermatitis occurring on the hands, and hyperkeratotic hand dermatitis, which are thickened, scaly, red plaques, similar to psoriasis, on the hands. The impact of hand eczema on patients can be significant, leading to work absences or disability, social stigmatization, and psychosocial distress.

About ARQ-252
ARQ-252 is a potent and highly selective topical, small molecule inhibitor of Janus kinase type 1 (JAK1). Many inflammatory cytokines and other signaling molecules rely on the JAK pathway, and specifically JAK1, which plays a central role in immune system function. Inhibition of JAK1 has been shown to treat a range of inflammatory diseases, including rheumatoid arthritis, Crohn’s disease, and atopic dermatitis. The Company believes that due to its high selectivity for JAK1 over JAK2, ARQ-252 has the potential to effectively treat inflammatory diseases without causing the hematopoietic adverse effects typically associated with JAK2 inhibition. In 2018, Arcutis exclusively licensed the active pharmaceutical ingredient in ARQ-252 for all topical dermatological uses in the United States, Europe, Japan and Canada from Jiangsu Hengrui Medicine Co., Ltd. of China. In mid-2019, Hengrui completed a Phase 2 study in rheumatoid arthritis that used the same active pharmaceutical ingredient as in ARQ-252 but dosed orally. The results confirmed that this active pharmaceutical ingredient is a highly potent inhibitor of JAK1 based on the drug’s impact on rheumatoid arthritis, and was generally well tolerated at exposures well above those expected with topical administration of ARQ-252. Reistone Biopharma, a subsidiary of Hengrui, is also studying the oral formulation as a potential treatment for alopecia areata.

About Arcutis - Bioscience, applied to the skin.

Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a medical dermatology company developing innovative treatments for patients with immune-mediated dermatological diseases and conditions. The company is leveraging recent advances in immunology and inflammation to develop differentiated therapies against biologically validated targets to solve persistent treatment challenges in serious diseases of the skin. Arcutis’ robust pipeline includes four novel drug candidates currently in development for a range of inflammatory dermatological conditions. The company’s lead product candidate, topical roflumilast, has the potential to revitalize the standard of care for plaque psoriasis, atopic dermatitis, scalp psoriasis, and seborrheic dermatitis. For more information, visit https://www.arcutis.com or follow the company on LinkedIn and Twitter.

Forward Looking Statements
This press release contains "forward-looking" statements, including, among others, statements regarding the potential for ARQ-252 to treat hand eczema without causing the adverse effects associated with other JAK inhibitors; and the anticipated timing of the topline data of the Phase 2b portion of the study. 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 Annual Report on Form 10-K filed with U.S. Securities and Exchange Commission (SEC) on March 19, 2020, as well as any 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.

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