Arcutis Completes Enrollment in Phase 1/2b Study Evaluating ARQ-252 in Chronic Hand Eczema

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- ARQ-252 is a potent and highly selective topical JAK1 inhibitor offering potential safety advantages over less selective JAK inhibitors
- Hand eczema is the most common skin disease affecting the hands, impacting more than 8 million Americans
- Topline data now anticipated by mid-2021

WESTLAKE VILLAGE, Calif., Oct. 26, 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 completed enrollment in its 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. Arcutis has updated its projections and now anticipates announcing topline data from this trial by mid-2021.

“We were pleased with the speed with which this trial enrolled, underscoring the high unmet need for new treatments to treat this chronic skin disease that can cause significant skin irritation and discomfort and can have a negative impact on a patient’s quality of life,” said Patrick Burnett, M.D., Ph.D., FAAD, Arcutis’ Chief Medical Officer. “More than eight million people in the U.S. suffer from hand eczema, and patients often have to make trade-offs between drug efficacy, safety, and tolerability with current available treatments. ARQ-252 has demonstrated robust potency and high selectivity for JAK1 over JAK2, thereby giving it the potential to deliver efficacy without causing the side effects typical of other less selective JAK inhibitors. Given this, we believe ARQ-252 has the potential to reduce the need to compromise between safety and efficacy.”

In April, Arcutis began the Phase 1 portion of this 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 seven subjects with chronic hand eczema. In July, the Company began the Phase 2b portion of the study to 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. Enrollment of the Phase 2b portion is now complete with 223 subjects. The Company expects to report topline data by mid-2021.

About Hand Eczema
Hand eczema is a common inflammatory skin disease with prevalence estimated at up to 2.5% of the population, and is the most common skin disease affecting the hands. Symptoms of hand eczema can vary 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 2b 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 in patients with chronic hand eczema. Reistone Biopharma, a subsidiary of Hengrui, is also studying the oral formulation as a potential treatment for alopecia areata, Crohn’s disease, ulcerative colitis and atopic dermatitis.

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 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 Form 10-Q filed with U.S. Securities and Exchange Commission (SEC) on August 11, 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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