Arcutis Provides Update on Phase 2a Clinical Trial Evaluating ARQ-252 Cream as a Potential Treatment for Vitiligo

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- Formulation-related observations from ARQ-252 trial in chronic hand eczema informed early termination of Phase 2a ARQ-252 trial in vitiligo
- Company progressing new formulation with goal of greater drug delivery to targets in the skin

WESTLAKE VILLAGE, Calif., July 01, 2021 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), today announced its decision to terminate the recently initiated Phase 2a clinical trial evaluating ARQ-252, a topical small molecule inhibitor of Janus kinase type 1 (JAK1), as a potential treatment for vitiligo (ARQ-252-213). Arcutis' decision is based on further analyses of the ARQ-252 drug formulation used in both this vitiligo study and the recently completed Phase 2b study evaluating ARQ-252 for the treatment of chronic hand eczema (ARQ-252-205).

As previously announced, the Phase 2b chronic hand eczema study did not meet its primary endpoint, with none of the ARQ-252 arms achieving statistical significance versus vehicle. Further analyses of that study pointed toward inadequate local drug delivery to the skin as a key driver of the lack of efficacy.

"While we are disappointed to terminate this vitiligo study, we believe topical JAK inhibition remains a promising strategy for the treatment of both chronic hand eczema and vitiligo, and that ARQ-252 has potential as a new treatment for both diseases. Published clinical data for other topical JAK inhibitors have shown encouraging results in both indications. Furthermore, the active pharmaceutical ingredient in ARQ-252 -- SHR0302 -- is a potent and highly selective JAK1 inhibitor that has demonstrated efficacy and safety as an investigational oral formulation in other inflammatory conditions such as rheumatoid arthritis and atopic dermatitis," said Patrick Burnett, M.D., Ph.D., FAAD, Chief Medical Officer of Arcutis. "We have already made good progress in reformulating ARQ-252 to potentially deliver much more active drug to targets in the skin and hope to re-enter the clinic with this reformulated version in the not-too-distant future. We want to thank the patients and investigators in the vitiligo study for their participation."

The vitiligo study is not being terminated for any safety or tolerability reasons. ARQ-252 has been safe and well-tolerated, and no unexpected safety concerns have been identified.

About ARQ-252
ARQ-252 is a 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. In 2020, Reistone Biopharma, a subsidiary of Hengrui, announced positive topline results from a Phase 2 clinical trial evaluating the oral version of the active ingredient in ARQ-252 for the treatment of moderate-to-severe atopic dermatitis. Reistone Biopharma is also studying the oral formulation as a potential treatment for alopecia areata, Crohn's disease, and ulcerative colitis.

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 seven clinical programs for a range of inflammatory dermatological conditions, with our first NDA submission by the end of 2021 and three more Phase 3 clinical data readouts anticipated over the next 18 months. The company's lead product candidate, topical roflumilast, has the potential to advance the standard of care for plaque psoriasis, atopic dermatitis, scalp psoriasis, 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, including, among others, statements regarding the potential for Arcutis to conduct clinical trials with a reformulated ARQ-252 and for the reformulated product to treat chronic hand eczema and vitiligo. 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 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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