Arcutis Announces First Patient Enrolled in Phase 2a Clinical Trial Evaluating ARQ-252 as a Potential Treatment for Vitiligo

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- ARQ-252 is a potent and highly selective topical JAK1 inhibitor offering potential safety advantages over less selective JAK inhibitors
- Topline data anticipated second half 2023
- Vitiligo affects approximately 1.3 million patients in the U.S.

WESTLAKE VILLAGE, Calif., March 18, 2021 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a late-stage biopharmaceutical company focused on developing and commercializing treatments for unmet needs in immune-mediated dermatological diseases and conditions, or immuno-dermatology, today announced enrollment of the first patient in a Phase 2a clinical trial evaluating ARQ-252 as a potential treatment for vitiligo. ARQ-252 is a potent and highly selective topical small molecule inhibitor of Janus kinase type 1 (JAK1).

"Initiation of this clinical trial marks an important milestone toward addressing the unmet need for new treatments for a chronic skin disease that can negatively impact a patient's quality of life," said Patrick Burnett, M.D., Ph.D., FAAD, Arcutis' Chief Medical Officer. "Approximately 1.3 million people in the U.S. suffer from vitiligo, and there is currently no FDA-approved treatment. Physicians typically use off-label combinations of older agents, but these options generally lead to only limited improvement, and most patients are dissatisfied with their treatment options. Early data with other topical JAK inhibitors suggest this target is effective in treating vitiligo, and 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. This Phase 2a study will evaluate ARQ-252 in combination with at-home narrowband UVB phototherapy, and it is our hope that this approach can provide meaningfully better efficacy to patients with this very challenging condition."

This Phase 2a study is a parallel group, double blind, vehicle-controlled study of the safety and efficacy of ARQ-252 0.3% cream either with or without narrowband UVB (NB-UVB) phototherapy treatment in approximately 500 subjects with non-segmental facial vitiligo. The primary endpoint of the study is the proportion of subjects achieving Facial Vitiligo Area Scoring Index-75 (F-VASI-75), which is ≥ 75% improvement from baseline in F-VASI at week 24.

Arcutis is also developing ARQ-252 0.3% cream as a potential treatment for chronic hand eczema and expects to report topline data from a Phase 1/2b study in mid-2021. In October 2020, Arcutis announced that enrollment had been completed in this Phase 1/2b study to assess the safety and efficacy of ARQ-252 0.1% cream once daily and ARQ-252 0.3% cream once daily or twice daily versus vehicle applied once daily or twice daily for 12 weeks to patients with chronic hand eczema.

About Vitiligo
Vitiligo is an auto-immune condition that occurs in as much as 1% of the U.S. population and is characterized by the loss of natural skin color or discolored patches on various parts of the body, including hair and mucous membranes. The cause of vitiligo is unknown but results when the skin's pigment producing cells (melanocytes) are targeted by the body's immune system. Vitiligo often starts on the hands, feet, or face and is typically progressive. It is a skin disease that affects people of all skin types but may be more noticeable in people with darker skin. Because of the effect on the person's appearance, vitiligo can be life-altering and can have a substantial negative impact on the psychological well-being of patients and reduce quality of life. Vitiligo can lead to a poor body image, causing individuals to feel embarrassed or anxious about their skin and withdraw from social activities.

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. 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 - Bioscience, applied to the skin.

Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a late-stage biopharmaceutical company focused on developing and commercializing treatments for unmet needs in immune-mediated dermatological diseases and conditions, or immuno-dermatology. 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 become 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 ARQ-252's potential as a treatment for vitiligo; and expectations with regard to the timing of the Phase 2 clinical trial. 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 November 5, 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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