Arcutis Announces Enrollment of First Patient in Phase 1/2b Study of ARQ-252 in Patients with Chronic Hand Eczema

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- ARQ-252 is a Potent Topical Small Molecule Inhibitor of JAK1
- High Selectivity for JAK1 over JAK2
- JAK Inhibition a Biologically Validated Target for Treatment of Hand Eczema

WESTLAKE VILLAGE, Calif., April 21, 2020 (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 that it has enrolled the first patient in 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.

“Hand eczema is one of the most common skin diseases, affecting approximately 8 million Americans, and currently there are no FDA-approved therapies for this affliction,” said Howard Welgus, M.D., Arcutis’ Chief Medical Officer. “We are delighted to begin enrollment in this Phase 1/2b study of ARQ-252, our topical JAK1 inhibitor, in adult patients with chronic hand eczema. JAK inhibition has been shown to treat a range of inflammatory diseases including hand eczema, and we believe that, due to its demonstrated potency and high selectivity for JAK1 over JAK2, ARQ-252 has the potential to treat hand eczema without causing the adverse effects that may be associated with other less selective JAK inhibitors.”

The Phase 1 portion of the study will 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 the study will assess the safety and efficacy of ARQ-252 cream 0.1% once daily and ARQ-252 cream 0.3% once daily and twice daily versus vehicle applied once daily and twice daily for 12 weeks to patients with chronic hand eczema. The Company expects to begin the Phase 2b portion of the study in the second half of 2020, and expects topline data in the second half of 2021.

About Hand Eczema
Hand eczema is a common, predominantly inflammatory, skin disease. It is the most common skin disease affecting the hands, with prevalence estimated at up to 2.5% of the population. Hand eczema is characterized variously by redness, fluid filled blisters or bumps, scaling, cracking, itching and pain occurring on the hands, especially the palms. It is a diverse syndrome, incorporating dyshidrotic eczema, an immune disease possibly related to atopic dermatitis; irritant contact dermatitis of the hands, which is caused by occupational irritants such as chemicals; 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, psoriasis, Crohn’s disease, and atopic dermatitis. The Company believes that due to its high selectivity for JAK1 over JAK2, ARQ-252 will be able 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.

About Arcutis - Bioscience, applied to the skin.
Arcutis 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. Arcutis exploits recent innovations in inflammation and immunology to develop potential best-in-class therapies against validated biological targets, leveraging our deep development, formulation and commercialization expertise to bring to market novel dermatology treatments, while maximizing our probability of technical success and financial resources. Arcutis is currently developing three novel compounds (topical roflumilast cream (ARQ-151), topical roflumilast foam (ARQ-154) and ARQ-252) for multiple indications, including psoriasis, atopic dermatitis, seborrheic dermatitis and eczema. For more information, please visit www.arcutis.com or follow the Company on LinkedIn.

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; the anticipated timing of beginning the Phase 2b portion of the Phase 1/2b study; 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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