Arcutis Announces Inclusion of Children in On-going Pivotal Phase 3 Clinical Trials Evaluating Topical Roflumilast (ARQ-151) as a Potential Once Daily Topical Treatment for Plaque Psoriasis

March 16, 2020

- FDA requests study amendment to allow inclusion of children ages 2 to 11 years in the DERMIS-1 and DERMIS-2 trials
- Strong safety profile supported population expansion in pivotal Phase 3 trials
- Topical Roflumilast potential “Best in Class” topical PDE4 inhibitor
- Phase 3 trials’ topline data anticipated first half 2021

WESTLAKE VILLAGE, Calif., March 16, 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, at the request of the U.S. Food and Drug Administration (FDA), Arcutis has submitted a protocol amendment to the FDA to include children ages 2 to 11 years old in the Company’s on-going DERMIS-1 and DERMIS-2 pivotal Phase 3 clinical trials evaluating topical roflumilast cream as a potential topical treatment for plaque psoriasis. The trials’ previous inclusion criteria included patients ages 12 and above.

“After consultations with the FDA, we are delighted that the Agency requested expanding the inclusion criteria to include children as young as two years of age in our pivotal Phase 3 clinical trials in patients with plaque psoriasis,” said Howard Welgus, MD, Chief Medical Officer at Arcutis. “Many treatment options approved for adults for this chronic skin condition have not been studied in children, a population where additional caution regarding safety and tolerability is paramount. As no cure for psoriasis exists, patients and dermatologists need new and better topical treatment options to manage this chronic inflammatory condition. Based on its safety, tolerability and efficacy profile in our completed clinical trials, we believe topical roflumilast has the potential to be both the best-in-class topical PDE4 inhibitor and the only topical PDE4 inhibitor approved for plaque psoriasis, including in children."

Topical roflumilast cream (ARQ-151) contains the highly potent and selective phosphodiesterase type 4 (PDE4) inhibitor roflumilast, which was approved globally for the systemic treatment of chronic obstructive pulmonary disease (COPD) in 2011, and has shown greater potency based on IC50 values (a non-clinical measure of a drug's potency) than other PDE4 inhibitors. PDE4 is an intracellular enzyme that increases the production of pro-inflammatory mediators and decreases production of anti-inflammatory mediators, and has been implicated in a wide range of inflammatory diseases including psoriasis, eczema, and COPD. PDE4 is an established target in dermatology, and other PDE4 inhibitors have been approved by the FDA for the topical treatment of atopic dermatitis and the systemic treatment of plaque psoriasis.

About the ARQ-151-301 (DERMIS-1) and ARQ-151-302 (DERMIS-2) Phase 3 Program
Arcutis is currently conducting a Phase 3 clinical program with topical roflumilast cream, including two ongoing Phase 3 clinical trials (Studies ARQ-151-301 and ARQ-151-302) to support registration with the FDA. The studies, referred to as the “Trials of P ***DE***4 inhibition with ***R***oflumilast for the ***M***anagement of Plaque Psoria***sis***” (DERMIS-1, DERMIS-2), are identical Phase 3 randomized, parallel, double-blind, vehicle-controlled, multi-national, multi-center studies in which 0.3% topical roflumilast cream or vehicle cream are applied once daily for 8 weeks to subjects aged 2 and above with mild, moderate or severe chronic plaque psoriasis involving between 2% and 20% body surface area. The studies will each enroll approximately 400 patients. The primary endpoint of the studies is Investigator Global Assessment (IGA) Success, defined as an IGA score of clear or almost clear and at least a 2-grade improvement from baseline at week 8 on the IGA score. Multiple secondary endpoints will also be evaluated, including Intertriginous IGA (I-IGA) Success, and improvements in Psoriasis Area Severity Index (PASI), itch as measured by the Worst Itch-Numerical Rating Scale (WI-NRS) and patient perceptions of symptoms as measured by the Psoriasis Symptoms Diary (PSD). The company anticipates topline data from the Phase 3 studies in the first half of 2021.

About Psoriasis
Psoriasis is a common, non-contagious, immune-mediated skin disease that affects approximately 8.6 million patients in the United States. About 90% of patients with psoriasis have chronic plaque psoriasis, which is characterized by raised, red areas of skin covered with a silver or white layer of scale. Psoriatic plaques can appear on any area of the body, but most often appear on the scalp, knees, elbows, trunk, and limbs, and are often itchy and sometimes painful. Plaques in certain anatomical areas present particular treatment challenges, including the face, elbows and knees, scalp, and intertriginous regions such as the groin, axillae and inframammary areas. Although uncommonly diagnosed in children and adolescents, particularly in children under the age of 5, plaque psoriasis occurs in approximately 0.5% of children and adolescents.

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, topical roflumilast foam 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 topical roflumilast to be a best-in-class topical PDE4 inhibitor; the potential for topical roflumilast to be approved for plaque psoriasis, including the potential for approval for use in children; and the anticipated timing and results from the pivotal Phase 3 trials. 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 Registration Statement on Form S-1 filed with U.S. Securities and Exchange Commission (SEC) on January 21, 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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