Arcutis Announces ARQ-154 Program for Seborrheic Dermatitis and Enrollment of First Patient in Phase 2 Proof of Concept Clinical Trial

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- ARQ-154 potential "Best in Class" topical PDE4 inhibitor in foam formulation
- Seborrheic dermatitis affects over 6 million U.S. patients
- Phase 2 topline data anticipated 2H 2020

Westlake Village, CA, December 5, 2019 – Arcutis Biotherapeutics, Inc. (Arcutis), a privately held clinical-stage biopharmaceutical company focused on developing and commercializing treatments for unmet needs in immune-mediated dermatological diseases and conditions, or immuno-dermatology, today provided details on the ARQ-154 clinical development program for seborrheic dermatitis. ARQ-154 is a once-daily topical foam formulation of a highly potent and selective phosphodiesterase type 4 inhibitor (PDE4 inhibitor) that the Company is developing particularly to treat inflammatory dermatoses in hair-bearing areas of the body such as the scalp. The Company also announced that it has enrolled the first patient in a Phase 2 proof of concept clinical trial evaluating the compound as a potential treatment for seborrheic dermatitis.

Frank Watanabe, Arcutis' President and Chief Executive Officer, commented: "Although there are approximately 6.5 million seborrheic dermatitis patients in the United States, and more than one million receive prescription topical treatment from a dermatologist each year, this is one of the most neglected diseases in dermatology. We believe a significant opportunity exists for novel therapies, particularly for patients who don't adequately respond to existing treatments, or who have disease in the area around their eyes, an especially difficult area to treat. We believe ARQ-154 may provide a new treatment option for physicians and patients, with the potential to show significant symptomatic improvement, while maintaining a low risk of toxicity or side effects, the ability for treatment in the periocular area, and suitability for chronic use, all in a foam formulation that is convenient to use on hair-bearing areas of the body."

ARQ-154 is a topical foam formulation of a highly potent and selective PDE4 inhibitor (roflumilast). Roflumilast has been approved by the U.S. Food and Drug Administration (FDA) for systemic treatment to reduce the risk of exacerbations of chronic obstructive pulmonary disease (COPD) since 2011. Roflumilast has shown greater potency based on IC50 values (a non-clinical measure of a drug's potency) than any other disclosed PDE4 inhibitor. 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 or the systemic treatment of plaque psoriasis.

Arcutis believes ARQ-154 has significant potential as a seborrheic dermatitis treatment. ARQ-154 is nearly identical to ARQ-151, Arcutis' investigational topical cream PDE4 inhibitor that has demonstrated symptomatic improvement and a favorable tolerability profile based on the Company's clinical trials in plaque psoriasis. Based on the profile of ARQ-154 and prior clinical data with ARQ-151, Arcutis has initiated a Phase 2 proof of concept clinical trial to evaluate ARQ-154 as a potential treatment for seborrheic dermatitis.

The trial is a Phase 2, 8-week, multi-center, multi-national, double blind, vehicle-controlled, proof of concept study of the safety and efficacy of ARQ-154 0.3% topical foam administered once-daily in approximately 150 patients with seborrheic dermatitis. The primary endpoint of the trial is achievement of an Investigator Global Assessment Scale (IGA) score of 'clear' or 'almost clear' plus a 2-grade improvement from baseline at week 8. This global assessment scale has five severity grades reported from 0-4 and defined as Clear (0), Almost Clear (1), Mild (2), Moderate (3), Severe (4). The Company anticipates topline data from the trial in the second half of 2020.

About Seborrheic Dermatitis

Seborrheic dermatitis is a common, chronic or recurrent skin condition that causes red patches covered with large, greasy, flaking yellow-gray scales, and persistent itch. Seborrheic dermatitis occurs most often on the scalp, face (especially on and around the nose, eyebrows, and eyelids), ears, upper chest and back. A milder form of seborrheic dermatitis is common dandruff.

About Arcutis - Bioscience, applied to the skin.

Arcutis is a clinical-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 (ARQ-151, 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.

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