



Arcutis, Inc.'s ARQ-151 Development Program for Atopic Dermatitis

- ARQ-151 Potential "Best in Class" Topical PDE4 inhibitor
 - Phase 1 Study in Atopic Dermatitis Completed
 - Phase 2 Study Initiation Anticipated June 2019

Westlake Village, CA, May 16, 2019 – [Arcutis, Inc.](#), a privately held immuno-dermatology drug development company addressing significant unmet needs in dermatology today provided details on the [ARQ-151](#) clinical development program for [atopic dermatitis](#). ARQ-151, Arcutis' lead product candidate, is a highly potent and selective phosphodiesterase type 4 inhibitor ("PDE4 inhibitor") once-daily topical cream. The Company anticipates initiating a Phase 2 study evaluating the compound as a potential treatment for atopic dermatitis (AD) in June 2019.

[Frank Watanabe](#), Arcutis' President and Chief Executive Officer, commented: "In 2017, approximately ten million atopic dermatitis patients were diagnosed in the United States with approximately 5.5 million of those patients receiving topical therapy. We believe a substantial need exists for a therapy that offers greater efficacy, the ability to treat chronically, and good safety and tolerability, all of which we believe ARQ-151 may provide."

ARQ-151 is a topical cream formulation of a highly potent and selective PDE4 inhibitor (roflumilast) that has been approved for the systemic treatment of chronic obstructive pulmonary disease (COPD) since 2011 and that is many-fold more potent than any other disclosed PDE4 inhibitor. Phosphodiesterase type 4 (PDE4) is an intracellular enzyme that increases the production of proinflammatory 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 U.S. Food and Drug Administration for the topical treatment of atopic dermatitis or the systemic treatment of plaque psoriasis.



Arcutis believes ARQ-151 has significant potential as an atopic dermatitis treatment given PDE4 is a proven mechanism to treat AD and that ARQ-151 is 50- to 300- fold more potent than the approved PDE4 inhibitors. Arcutis has completed a Phase 1 pharmacokinetic (PK) study of ARQ-151 in AD patients, which provided an early signal of efficacy with an approximate 50% reduction in AD lesion area after only 2 weeks of treatment. ARQ-151 causes little to no irritation on application, and has shown no signs of significant local skin reactions in clinical studies.

Based on the strength of the Phase 1 AD PK study data and the compound's profile, Arcutis anticipates initiating a Phase 2 study of ARQ-151 in AD in June 2019.

About Atopic Dermatitis

Atopic dermatitis (AD) is the most common type of eczema, occurring in approximately six percent of the U.S. population. AD is characterized by a defect in the skin barrier, which allows allergens and other irritants to enter the skin, leading to an immune reaction and inflammation. This reaction produces a red, itchy rash, most frequently occurring on the face, arms and legs, and the rash can cover significant areas of the body, in some cases half of the body or more. The disease typically begins in early childhood and is chronic, but many sufferers outgrow it as they age, although it persists into adolescence and even adulthood in some individuals. The rash causes significant pruritus (itching), which can lead to skin damage caused by scratching or rubbing. Since a large percentage of AD patients are very young children, safety is a particularly important consideration in treatment selection.

About Arcutis - Bioscience, applied to the skin.

Arcutis is a clinical-stage biopharmaceutical company focused on developing and commercializing drugs that address significant unmet medical needs in immuno-dermatology. Arcutis exploits recent innovations in inflammation and immunology to develop best-in-class molecules against biologically validated targets, leveraging our industry-leading development expertise to bring to market novel dermatology treatments in less time, at lower cost and with lower risk than other approaches.



Arcutis is currently developing two novel compounds (ARQ-151 and ARQ-250) for multiple indications including, psoriasis, atopic dermatitis and eczema. For more information, please visit www.arcutis.com or follow the Company on [LinkedIn](#).

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