Arcutis Announces Initiation of Phase 2a Clinical Trial of ARQ-151 as a Potential Topical Treatment for Atopic Dermatitis

- ARQ-151 Potential “Best in Class” Topical PDE4 inhibitor
- ARQ-151 is 50- to 300-fold more potent than approved PDE4 inhibitors
- Phase 2a Topline Data Anticipated Year End 2019

Westlake Village, CA, June 3, 2019 – Arcutis, Inc., a privately held immuno-dermatology drug development company addressing significant unmet needs in dermatology today announced that it has enrolled the first patient in a Phase 2a clinical trial evaluating ARQ-151 as a potential treatment for atopic dermatitis (AD). ARQ-151, Arcutis’ lead product candidate, is a highly potent and selective phosphodiesterase type 4 inhibitor (“PDE4 inhibitor”) once-daily topical cream.

Frank Watanabe, Arcutis’ President and Chief Executive Officer, commented: “We believe ARQ-151 has significant potential as an atopic dermatitis treatment given PDE4 is a proven mechanism to treat AD coupled with ARQ-151’s 50- to 300- fold potency advantage over the currently FDA-approved PDE4 inhibitors and the excellent tolerability ARQ-151 has demonstrated in the clinic. ARQ-151 has the potential to address the substantial need we believe exists for an atopic dermatitis therapy that offers greater efficacy, the ability to treat chronically, and good safety and tolerability. We anticipate having topline data from this study by the end of this year.”

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.

The Phase 2a clinical trial is a parallel group, double blind, vehicle-controlled study in which ARQ-151 cream 0.05% or ARQ-151 cream 0.15% or vehicle is applied once a day for 28 days to adolescent and adult subjects with atopic dermatitis. The study will assess the safety, pharmacokinetics (PK) and efficacy of the two dose levels of ARQ-151. The primary outcome measurement will be change from
baseline in Eczema Area and Severity Index (EASI) Total Score at week 4. Multiple secondary outcomes measures will also be assessed, including, among others, EASI Total Score Percent Change, Validated Investigator Global Assessment scale for Atopic Dermatitis (vIGA-AD) Score, and WI-NRS pruritus score.

**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](http://www.arcutis.com) or follow the Company on [LinkedIn](https://www.linkedin.com).
Contact:
John W. Smither
Chief Financial Officer
ismither@arcutis.com

Investors and Media:
Derek Cole
720.785.4497
derek.cole@IRadvisory.com

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