Arcutis Announces Enrollment of Last Patient in Phase 2a Clinical Trial of ARQ-151 Cream as a Potential Topical Treatment for Atopic Dermatitis

---

- Phase 2a topline data anticipated by year end 2019
- ARQ-151 potential "Best in Class" topical PDE4 inhibitor
- Demonstrated potency advantage of 25x to greater than 300x compared to two FDA approved PDE4 inhibitors

Westlake Village, CA, October 9, 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 announced that it has completed enrollment of a Phase 2a clinical trial evaluating ARQ-151 as a potential treatment for atopic dermatitis (AD). ARQ-151, Arcutis' lead product candidate, is a once daily topical cream formulation of roflumilast, a highly potent and selective Phosphodiesterase type 4 inhibitor (PDE4), which we are developing for plaque psoriasis and atopic dermatitis.

Howard Welgus, M.D., Arcutis' Chief Medical Officer, commented: "We are delighted with the rapid pace of enrollment in this study, which started in June of this year. We believe ARQ-151 has significant potential as an atopic dermatitis treatment given that PDE4 inhibition is a well-established mechanism to treat AD, coupled with ARQ-151's potency advantage of 25x to in excess of 300x compared to the potency of the two FDA-approved PDE4 inhibitors and the excellent tolerability ARQ-151 previously demonstrated in our trials in psoriasis as well as in our Phase 1 study in AD. Based on the clinical data generated to date, we believe ARQ-151 has the potential to address the substantial need that we believe exists for an atopic dermatitis topical therapy that offers efficacy in-line with high-potency steroids, a favorable tolerability profile, the ability to treat chronically, and that has little to none of the application site reactions associated with many existing treatments. We anticipate having topline data from this study by the end of this year."

The ARQ-151-212 study is a multi-center, multi-national, double blind, vehicle-controlled Phase 2a study, in which 136 adolescents (ages 12 and above) and adults with atopic dermatitis covering between 1.5% and 35% body surface area (BSA) were randomized to receive once a day topical applications for 4 weeks of: (1) ARQ-151 cream 0.15%, or (2) ARQ-151 cream 0.05%, or (3) vehicle. The study will assess the safety, pharmacokinetics (PK) and efficacy of the two dose levels of ARQ-151. The primary efficacy endpoint is change from baseline in Eczema Area and Severity Index (EASI) Total Score at week 4. Multiple secondary outcome measures will also be assessed, including, among others, percent change from baseline in EASI Total Score, achievement of a 50% or greater improvement in EASI (EASI50) score from baseline, and Worst Itch-Numerical Rating Scale (WI-NRS) pruritus score.

About ARQ-151

ARQ-151 is a topical cream formulation containing roflumilast, a PDE4 inhibitor, that we are developing to treat plaque psoriasis, including intertriginous psoriasis, and atopic dermatitis. PDE4 is an intracellular enzyme that regulates the production of pro-inflammatory and anti-inflammatory cytokines and cell proliferation. Roflumilast is a potent PDE4 inhibitor that was approved by the U.S. Food and Drug Administration (FDA) for systemic treatment to reduce risk of exacerbation 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.

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. Disease onset is most common by 5 years of age, and we estimate that approximately 60% of patients suffering from AD

are pediatric patients. The rash causes significant pruritus (itching), which can lead to skin damage caused by scratching or rubbing. Given that most of the patients are pediatric, the safety and tolerability of AD therapies is paramount.

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 two novel compounds (ARQ-151 and ARQ-252) for multiple indications including psoriasis, atopic dermatitis and eczema. For more information, please visit www.arcutis.com or follow Arcutis on LinkedIn.

Contact:
John W. Smither
Chief Financial Officer
jsmither@arcutis.com

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

###